

# **Human Organ Donation and Transplantation Survey**

COUNTRY:			
INFORMATION PROVIDED BY:			
Name:			
Position:			
Organization: Address:			
Telephone:	Fax no.:		
E-mail:			
Date:			
BASIC INFORMATION OF THE COUNTRY:			
- Is there a functioning <sup>1</sup> transplantation programme?		<u>Yes</u>	<u>No</u> □
- 13 there a functioning transplantation programme?		_	J
- Is there a functioning programme for organ donation	from deceased persons?		
- Is there a functioning programme for organ donation	n from living donors?		

<sup>&</sup>lt;sup>1</sup> Definition of Functioning programme: programme performing or able to perform its regular function

# A 1/ ORGANIZATIONAL SYSTEM

nere a ( al level		ernment recognized authority responsible	e for overseeing donat	ion and/or transplantation at
Yes		If yes, please tick the appropriate for:	Donation Transplantation Both	
NI.		Name (s):		
No				
		ific organization, institution or agency res al level?	sponsible for organ do	nation and/or transplantation
Yes		If yes, please provide name (s):		
No		If not, please skip to question 3.		
<b>2.1</b> W	Pri Pu	sector provides funding for this organizativate  blic   th	ation/institution/agency	/?
<b>2.2</b> Do	oes t	the organization/institution/agency report	to the Ministry of Hea	ılth?
	Ye No		n:	
<b>2.3</b> PI	ease	e tick the activities which this organization	n/institution/agency is	responsible for:
	- S - W - C - D - T - C	Promotion of organ donation Setting up protocols, guidelines, recomme Vaiting List management Coordination of organ procurement Organ allocation Conors registry/registries Fransplant follow-up registries Other: Please specify  additional information if there are different ions having different roles in donation and	ent (more than one) go	

<b>4.</b> Is t	the country affi	liated with a	an international organ all	ocation	organization?	
	Yes		please specify which one	:		
	No					
<b>5.</b> Are	there Ethical (	Committees	dealing with donation a	nd / or ti	transplantation activities?	
	Yes No					
	<b>5.1.</b> If yes, at	National	P (Please, <b>only</b> tick the h State / Regional / Fede spital		level of centralization)  □ □ □ □	
6. Is to level?		on/s respon	sible for managing orgar	n donati	ion and / or transplantation matters a	t national
		onation:		Yes No		
	For transplantation:					
	For be	oth (donatio	n and transplantation):	Yes No		
<b>7.</b> Are	there registrie	s to collect	socio-demographic, clini	cal and	l/or epidemiological data of the donor	rs?
	- Deceased - Living	Yes □ □	<u>No</u> □			

	w-up/outcomes registivel of centralization).	tries in pl	ace? (\	Whenever	the answer is Yes	s, please <b>only</b> tick the
<u>nignest</u> le	vei of certifalization).				Level	
- Post-tra	nsplant <u>recipient</u> follo		s <u>No</u>	National	Provincial/Regio	onal/State Local/Hospital
<b>D</b>	- Kidney - Liver - Heart - Lung - Pancreas			0		
-Post-trai	nsplant <u>Living dono</u> r f	-				П
	- Kidney - Liver - Lung					
9. Is there any se	urveillance system ba	sed on th	ne repo	rting of adv	verse events in o	rgan transplant recipients?
Y N	es 🔲 o 🖵					
<b>9.1</b> If yes	, please <b>only</b> tick the	highest l	evel of	centralizat	tion:	
	National Provincial / St Local / Hospit		gional /	Federal le	vel 📮	
10. Is there any sorgan transplant		ased on	the rep	orting of a	dverse reactions	in living organ donors and
	rgan transplant recipi ving organ donors	ents	<u>Ye</u>	es <u>No</u>		
10	0.1 If yes, please only	tick the	highes	t level of ce	entralization:	
	National Provincial / St Local / Hospit		gional /	Federal le	vel 🔲	
<b>11.</b> Please provide level, if there is a		mpetent	author	ity/ies over	seeing safety and	d quality matters at nationa

<b>12.</b> Is there a s	system	atic pul	olic educat	ional progra	am on c	lonatio	on and t	ransplan	itation a	t school le	vel?
	Yes No	<u> </u>									
13. Are there a	any trai	ining pr	ogrammes	within the	country	to ha	ırmonize	practice	es for sta	aff involved	d in:
Organ procure Organ transpla		n	Yes □ □	<u>No</u> □							
<b>14</b> . Are the foll			ses for <u>dec</u>	ceased don	<u>ors</u> bas	ed on	any pro	otocols o	r standa	ords or guid	delines at
national/pro	viriciai	ievei?								<u>Yes</u>	<u>No</u>
	14.1. [	Deceas	ed donor i	dentification	า						
	14.2. (	Criteria	for donor s	selection							
	<b>14.3.</b> 9	Screeni	ng for tran	smissible d	iseases	(tum	ours, inf	ections,	other)		
<b>15.</b> Are there r	nationa	ıl/provin	cial/local s	standard gu	idelines	for d	onor ev	aluation	in <u>living</u>	donation?	
	Yes No	<u> </u>									
<b>16.</b> Are there t in donations fro Q.18)											
	<b>16.1</b> S	Selection	n of recipie	ents:	Yes No						
	<b>16.2</b> C	Organ a	llocation:		Yes No						

 $<sup>\</sup>overline{^2}$  Maintaining public access to regularly updated comprehensive data and information.

17. What are the criteria, if any, that are a	applied to er	nsure a fair	and equi	table <b>orga</b> i	n allocation?	
<b>17.1</b> Clinical criteria (age, severity	17.1 Clinical criteria (age, severity, etc)					
<b>17.2</b> Compatibility (= absence of recipient antibodies antigens present in the transplant		oup				
17.3 Time on Waiting List						
17.4 Geographical criteria						
<b>17.5</b> Others (Specify):						
<b>18.</b> Are there Waiting Lists for:						
- Kidney - Liver - Heart - Lung	Yes N	)   				
18.1 If yes, at what level	are they ma	anaged?				
National Provincial /State / Regional / Fede Local/Hospital	<u>Kidney</u> □ eral □ □	<u>Liver</u> □ □		Heart	Lung	
19. Are there exclusion criteria for candid	lates to rece <u>Yes</u>	eive an orga <u>No</u>	n transp	lant?		
- Foreigners - Other	0	□ □ If y	es, pleas	se commer	nt:	
20. Is there any mechanism to ensure that  Yes □  No □	at confidenti	ality and pri	vacy of o	donors and	recipients are protected	

<b>21.</b> Is there a	mechanism	in place	at <u>natior</u>	<u>nal leve</u>	<u>I</u> to e	nsure th	nat:		
	<b>21.1</b> each o	organ <u>do</u>	<u>nor</u> is uni	iquely id	dentif	ied?	Yes No		
	<b>21.2</b> each organ <u>recipient</u> is uniquely identified?					Yes No			
	<b>21.3</b> each <u>c</u>	organ is	uniquely	identifie	ed?		Yes No		
<b>22.</b> Is there a	ny system or	mechar	nism in pla	ace to e	ensur	e tracea	bility?		
	Yes ☐ If No ☐	yes, ple	ase comr	ment: _					
<b>23.</b> Are organ	n procuremer	it expens	ses cover	ed by?	(Plea	ase tick	when ap	oply	<b>)</b> ):
	State Private Hea Recipients Other	alth Insu	rance		_ _ _ _ P	lease s <sub>l</sub>	pecify: _		
<b>24.</b> Are transp	olantation co State Private Hea Recipients Other		,						
<b>25.</b> Are recipi	ents navina f	or nost.	. tranenla	nt care	and (	druge?			
<b>20.</b> Are recipi	Yes No	-	•	Total		-	al 🗖		
Please	e comment if	needed	:						
<b>26.</b> Are live dand follow-up		for any	interventi	ion (dia	gnos	tic, thera	apeutic,	sur	gery) derived from the transplant
	Yes No	<u> </u>	If yes:		Tot	al 🛚	Partia	al	
Pleas	e comment if	needed							

Transplants performed abroad:
27. Is there any cooperation framework or agreement to allow patients to be transplanted abroad?
Yes □ No □
If yes, please comment under which programmes and specify the countries:
<b>28.</b> In case of recipients travelling abroad to be transplanted (under a cooperation framework or not): Is the recipients' follow-up assured in the country of origin upon their return?
Yes □ No □
29. Do recipients and living donors travel abroad together?
Yes, always Yes, sometimes No
29.1 Is the living donor follow-up assured upon his/her return?
Yes □ No □
30. Please use this space for further clarifications to any of the questions:

# • A 2/ LEGISLATION

ı	N		4	_	
ı	v	u	и	c	١,

"Legal requirement": includes, for example, legislation, decrees, ordinances, regulations, administrative procedures, governmental resolutions, other mandatory governmental requirements or requirements of any other entity specifically mandated by the government to adopt such requirements.

<b>31.</b> Are any aspects of	of organ donation	on and /or transpla	ntation covered by	any legal	requirement?	
Yes	☐ If Yes, Tir	me of Enactment:				
No						
<b>31.1</b> If yes, do	oes it cover the	following aspects?				
Organ	donation from	deceased persons		<u>Yes</u> □	<u>No</u> □	
Organ	donation from	living persons				
Alloca	tion					
Organ	Transplantatio	n				
Organ	Trafficking					
<ul> <li>32. Is the government currently intending to adopt new or revise any legal requirement on these subjects and/or on missing/unforeseen subjects?</li> <li>Yes  No  </li> <li>33. Do healthcare centres, hospital teams or units, or any other body which undertakes the following procedures, have to be officially authorized to do so (by the government or any other entity specifically mandated by the government to make these authorizations):</li> </ul>						
33.1- (	Organ retrieval	<u>Yes</u> □	No □			
other bodies that can			vity? government affilia Il not for profit	<u>Yes</u>	hospital teams, units or  No  □  □  □  □	

<b>33.2</b> - Organ transplantati	Ye on [	<u>es</u>	<u>No</u> □				
<b>33.2.1</b> If ye other bodies that can be authorized to pe			types of healthcare coity?	entres, ho	spital te <u>No</u>	ams, u	nits or
- No	ngoverr	nmental	government affiliated not for profit for profit	<u> </u>			
<b>34.</b> Is there a legal requirement for healt government the <u>transplants performed</u> w				or other b	odies to	report	to the
Yes 🖵 No							
35. Is death certification a legal requirem	ent for a	all deatl	ns that occur within th	e country	?		
Yes		No					
35.1 Is death certification	a legal ı	requirer	ment for some, but no	t all death	ns?		
Yes		No					
If yes, pl	ease inc	dicate ir	which context:				
<b>36.</b> Are the criteria for the determination	of death	n specifi	ed in any legal requir	ements?			
Yes		No					
If yes:						Yes	No
<b>36.1</b> Is the determination made on	the basi	is of ne	urological criteria (i.e.	brain dea	ath)?	<u>163</u>	
<b>36.2</b> Is the determination made on	the basi	is of circ	culatory / respiratory o	criteria (ci	rculatory	⁄ death) □	)?
Donation from deceased persons							
<b>37.</b> Is the type of consent (presumed or any legal requirements in the country?	explicit)	require	d for donations from c	leceased	persons	specif	ied in
Yes □ No	☐ If	f not, ple	ease skip to 38.				

37.1. If yes, which type of consent is r	needed 10	or the org	an donatio	on tro	m deceas	sea persons	5 <i>7</i> :
37.1.1 Presumed consent	Yes		No		If not, ple	ease skip to	37.1.2.
<b>37.1.1.a</b> Is there any of refusals, etc)?	legal me	chanism t	o express	a re	fusal to de	onate (e.g.	ID, registry
, ,	Yes [	<b>3</b>	No				
<b>37.1.1.b</b> Although prepractice, is explicit consent always r			•	for in	ı legislatic	on, as a mat	ter of
	Yes	<b>_</b>	No				
37.1.2 Explicit consent	Yes	_	No				
<b>37.1.2.a</b> Is the decision register in a personal official docum						ased) possil	ole to
register in a personal official docum	ent (e.g.	ib, anvin	Yes		No		
<b>37.1.2.b</b> Is the conse the deceased person:	nt by fam	nily or nex	t of kin su	fficie	nt to allov	the donati	on, when
- Did not express the will to	donate		Yes 🛚	<b>.</b>	No		
- Stated in the past the refus	al to don	ate	Yes 🛚	<b>3</b>	No		
<b>37.1.2.c</b> Does the ref donation, when the deceased person	•	amily or n	ext of kin	to au	thorize do	onation prev	ent the
- Did not express the intent t	o donate	:	Yes 🛚	<b>.</b>	No		
- Did express in the past the	intent to	donate	Yes 🛚	<b>3</b>	No		
<b>37.1.2.d</b> Is there any to be available for organ donation?	registry o	of identifie	ed donors	who	have alre	ady stated t	heir intent
to be available for organ deflation.			Yes		No		
37.2. Is the consent to organ donation	on valid f	or all orga	ans?				
Yes ☐ No ☐ Please comment: _							

<b>38.</b> Are incentives to payment or other rev						eased pers	son (in the form of	any monetary
	Yes			No				
<b>38.1</b> l	f yes, are they	regulat	ed by th	e gove	rnment?	•		
	Yes			No				
	Please comm	nent:						
<b>39.</b> Is there a legal regovernment the actu							or other bodies to	o report to the
Yes		No						
Living Donation								
40. Is unrelated living	g donation lega	ally peri	mitted?					
Yes		No						
<b>41.</b> Are there require	ements which a	re pre-	requisite	es for <i>li</i>	ving dor	nations? <u>Yes</u>	No	
41.1 Ethical (	Committee app	roval					<u>No</u> □	
41.2 Externa	l medical advic	е						
41.3 Judicial	approval							
<b>41.4</b> Psychia	tric evaluation	of the c	donor					
<b>41.5</b> Written	consent of the	donor						
<b>41.6</b> Other: F	Please identify:							
42. Is there a legal re	equirement to i	nform t	he living	g donor	of risks	and conse	quences of the do	onation?
Yes		No						

<sup>&</sup>lt;sup>3</sup> Actual donor as defined in the Critical pathways for organ donation (Madrid Resolution): A consented eligible donor **A**.In whom an operative incision was made with the intent of organ recovery for the purpose of transplantation. and/or **B**. From whom at least **one organ was recovered** for the purpose of transplantation. Note: For the purpose of filling out this questionnaire, please only consider the Actual donor **B**.

<b>43.</b> Are finance reward of more			ermitte	ed for living organ donation (that include monetary payment or
	Yes		No	
If yes:	<b>43.1</b> A	Are they specific	cally re	gulated by the government?
	Yes		No	
	<b>43.2</b> V	Vhat are permit	tted inc	centives?
If not:	43.3	Are incentives r	nonethe	eless offered or provided to potential living donors?
	Yes No	☐ Please co	mment	:
<b>44.</b> Are there	legal re	estrictions to the	e cover	rage of donation costs for the living donor?
	Yes No			
the healthcare	e centre	e, hospital team	n, unit c	alth system - at any level: national, provincial/regional, local - or for or any other body, to provide care to the living donor in case of of the donation?
	Yes		No	
		Please, spec	ify:	
<b>46.</b> Is there a	legal re	equirement for	follow-ı	up/outcomes registries of living donors?
	Yes		No	
<b>46.1.</b> l	f yes, is	s there a legal r	require	ment for including that information in an established registry?
	Yes		No	
<b>47.</b> Is there as requirement?	ny kind	of explicit proh	ibition	of organ trafficking / transplant commercialism in any legal
	Yes		No	

<b>47.1.</b> li	f yes, a	re the	re penalt	ies?				
	Yes		No					
<b>47.2.</b> li	f yes, p	lease	identify v	vhat is	specific	ally pro	hibited:	
<b>48.</b> Is import in authorized, pr								or transplantation purposes) ments?
	Autho	rized:	Yes		No		Not stated	
	Prohib	oited:	Yes		No		Not stated	
<b>48.1</b> If of your govern						y impor	rt / export of o	organs must be subject to the oversight
	Yes			No				
<b>48.2</b> If	not, do	es it c	ccur non	etheles	ss?			
	Yes			No				
General Com	ments (	(also p	lease pro	ovide de	etails w	hether	<b>legislation</b> is	not uniform across the country):

#### A 3/ ANNUAL ORGAN TRANSPLANTATION ACTIVITY

Where applicable, please specify No	ot available (NAV) or Not A	Applicable (NA)
Annual activity data corresponding to	o year:	
<b>49.</b> How many transplant centres are	, ,	Number of:
	<b>49.1</b> Kidney centres:	
	49.2 Liver centres:	
	49.3 Heart centres:	
	49.4 Lung centres:	
	49.5 Pancreas centres:	
	49.6 Small Bowel centres:	

## **50.** Actual deceased organ donors <sup>4</sup>:

Green columns: Whenever possible, please indicate the number of donors according to the following age categories: paediatric donors (under 15 years old); 15 - 59 years old; ≥ 60 years old.

	Total	(< 15 years)	(15 - 59 years)	(≥ 60 years)
Number of Actual deceased organ donors:				
<b>50.1</b> Number of Actual donors after brain death (DBD), i.e., actual deceased organ donors in whom death has been determined by neurological criteria:				
<b>50.2</b> Number of Actual donors after circulatory death (DCD), i.e, actual deceased organ donors in whom death has been determined by circulatory criteria:				

<sup>&</sup>lt;sup>4</sup> Actual deceased organ donor: As defined in the Critical pathways for organ donation (Madrid Resolution): A consented eligible donor **A**. In whom an operative incision was made with the intent of organ recovery for the purpose of transplantation. and/or **B**. From whom at least **one organ was recovered** for the purpose of transplantation. Note: For the purpose of filling out this questionnaire, please only consider the Actual donor **B**.

# **51.** Utilized deceased organ donors <sup>5</sup>:

Green columns: Whenever possible, please indicate the number of donors according to the following age categories: paediatric donors (under 15 years old); 15 - 59 years old; ≥ 60 years old.

	Total	(< 15 years)	(15 - 59 years)	(≥ 60 years)
Number of utilized deceased organ donors:				
<b>51.1</b> Number of utilized donors after brain death (DBD), i.e. utilized deceased organ donors in whom death has been determined by neurological criteria:				
51.2 Number of utilized donors after circulatory death (DCD), i.e., utilized deceased organ donors in whom death has been determined by circulatory criteria:				

<sup>&</sup>lt;sup>5</sup> Utilized deceased organ donor: An actual donor from whom at least one organ was transplanted. (The critical pathways for organ donation. The Madrid Resolution).

**52. TRANSPLANTATION ACTIVITY** (In this section please specify the number of transplants<sup>6</sup> performed only within your country for each item)

Right green column: Whenever possible, please indicate the number of paediatric transplants (<15 years old)

<b>52.1</b> <u>KIDNEY</u>		Number of transplants (including paediatric)	Number of paediatric transplants (< 15 years old)
	<b>Total</b> - all combinations from deceased persons (including kidney + any other organ, transplants from DBD and DCD, single and double kidney transplant):		
From deceased persons	From DBD:		
	From DCD:		
	Single:		
	Double <sup>7</sup> :		
	Total :		
From living donors	Related donors:		
	Unrelated donors:		
TOTAL (Total Deceased +	Total Living):		

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<sup>&</sup>lt;sup>6</sup> Definition of Organ Transplants: the transfer (engraftment) of human organs from a donor to a recipient with the aim of restoring function (s) in the body.

<sup>&</sup>lt;sup>7</sup> One double kidney transplant ("en bloc") is considered as one transplant.

<b>52.2</b> <u>LIVER</u>		Number of transplants (including paediatric)	Number of paediatric transplants (< 15 years old)
	<b>Total</b> - all combinations (including liver + any other organ, transplants from DBD and DCD, split):		
From deceased persons	From DBD:		
	From DCD:		
	Split <sup>8</sup>		
Domino <sup>9</sup>			
	Of lobe/or segment(s) from 1 donor		
From living donors	Of lobe/or segment(s) from 2 donors		
	Total:		
Total (Total Deceased +Total Liv	ring + Domino):		

<b>52.3</b> <u>HEART</u>	Number of transplants	Number of paediatric transplants
Total - all combinations (including heart + any other organ):	(including paediatric)	(< 15 years old)
Heart-lung <sup>10</sup>		

<sup>&</sup>lt;sup>8</sup> A split liver transplant is defined when a donor liver is divided into parts and transplanted into more than one recipient. (Modified from UNOS)

<sup>&</sup>lt;sup>9</sup> Domino Transplant

A procedure in which an organ is removed from one transplant candidate and immediately transplanted into a second patient, with the first patient receiving a new organ from a deceased donor. (HRSA/OPTN)

<sup>&</sup>lt;sup>10</sup> One heart-lung transplant is counted as one lung transplant, one heart transplant and one heart-lung transplant.

<b>52.4</b> <u>LUNG</u>		Number of transplants (including paediatric)	Number of paediatric transplants (< 15 years old)
	Total - all combinations (including lung + any other organ transplants, from DBD and DCD, single and double lung, heartlung):		
From deceased persons	From DBD:		
persons	From DCD:		
	Single lung:		
	Double lung <sup>11</sup> (including heart-lung):		
From living donors:			
TOTAL (Total Deceased	l + Total Living):		

52.5 PANCREAS	Number of transplants (including paediatric)	Number of paediatric transplants (< 15 years old)
Total - all combinations (including Pancreas alone, pancreas + any other organ, transplants from DBD and DCD):		
From DBD:		
From DCD:		
Pancreas alone:		
Kidney-Pancreas:		

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One double-lung transplant is considered as one transplant.

<b>52.6</b> <u>SMALL BOWEL</u>	Number of transplants (including paediatric)	Number of paediatric transplants (< 15 years old)
<b>Total</b> - all combinations (including small bowel + any other organ):		
Small bowel alone:		

**52.7** <u>TOTAL NUMBER OF RECIPIENTS TRANSPLANTED</u> in your country within the year indicated. E.g. For more than one organ transplanted into the same recipient: Kidney-Liver-Heart Transplant = count as one recipient.

		Number of recipients transplanted (including paediatrics)	Number of paediatric recipients transplanted (< 15 years old)
From deceased persons	Total - all combinations (from DBD and DCD) and more than one-organ transplanted		
From living donors			
TOTAL (Living + Deceas	sed):		

#### 53. WAITING LIST (WL):

#### **53.1 KIDNEY**

Number of patients awaiting a transplant (only active candidates) on 31st December:

Number of patients dead while on the WL during the year

the course of XXXX

XXXX

Number of patients included on the WL for the first time in

Total number of patients ever<sup>12</sup> active<sup>13</sup> on the WL during

<sup>&</sup>lt;sup>12</sup> Active at any moment during the year.

Active Candidate: A transplant candidate eligible to be considered for organ offers at a given point in time. Some transplant candidates are temporarily classified as "inactive" by their transplant center because they are medically unsuitable for transplantation or need to complete other eligibility requirements. (HRSA/OPTN)

indicated:	
Number of patients with end-stage renal disease (ESRD) on dialysis treatment on 31 <sup>st</sup> December (if no exact data available, please give estimated data and indicate that it is an estimation)	

### **53.2** LIVER

Number of patients included on the WL for the first time in the course of XXXX	
Total number of patients ever active on the WL during XXXX	
Number of patients awaiting a transplant (only active candidates) on 31st December	
Number of patients dead while on the WL during the year indicated:	

### **53.3** HEART

Number of patients included on the WL for the first time in the course of XXXX	
Total number of patients ever active on the WL during XXXX	
Number of patients awaiting a transplant (only active candidates) on 31st December	
Number of patients dead while on the WL during the year indicated:	

# **53.4** LUNG

	П
Number of patients included on the WL for the first time in	
the course of XXXX	
Total number of patients ever active on the WL during	
XXXX	
Number of patients awaiting a transplant (only active	
candidates) on 31st December	
Number of patients dead while on the WL during the year	
indicated:	

### **53.5** PANCREAS

Number of patients included on the WL for the first time in the course of XXXX	
Total number of patients ever active on the WL during XXXX	
Number of patients awaiting a transplant (only active candidates) on 31st December	
Number of patients dead while on the WL during the year indicated:	

# **53.6** SMALL BOWEL

Number of patients included on the WL for the first time in the course of XXXX	
Total number of patients ever active on the WL during XXXX	
Number of patients awaiting a transplant (only active candidates) on 31st December	
Number of patients dead while on the WL during the year indicated:	

# **54. TRANSPLANTS ABROAD**

<b>54.1</b> Number of resident patients in the reporting country, known to have been transplanted abroad from a living or deceased donor, within the year indicated:
<b>54.1.1</b> If any cases reported for 54.1, please provide information on the destination country countries:
<b>54.2</b> Number of resident living donors in the reporting country, known to have travelled abroad to donate, within the year indicated:
<b>54.2.1</b> If any cases reported for 54.2, please provide information on the destination country countries:
54.3 Additional information: