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Living tissue and organ donation by minors: suggestions to improve the regulatory framework in Europe

Reference:
LIVING ORGAN AND TISSUE DONATION BY MINORS: THE REGULATORY FRAMEWORK ACROSS EUROPE

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Summary:
Donation of bone marrow by minors is a standard procedure in many countries. In several non-European countries minors have also come into view as living organ donors. This article examines how living tissue and organ donation by minors is regulated across Europe. We first analyse how minors are protected in international legal instruments and transplantation guidelines. Subsequently, we examine how living tissue and organ donation by minors is regulated in the EU Member States, Norway and Switzerland. We point out that living tissue donation by minors is allowed in all 30 countries under consideration, with only slight differences in its regulation. By contrast, living organ donation by minors is currently only allowed in six European countries. In these countries, regulations differ widely with regard to the substantive and procedural safeguards that need to be fulfilled. We argue that the interests of minors would best be served if more European countries would allow living organ donation by minors, in exceptional circumstances and subject to a wide range of protective measures.

Key words: Best Interests, Comparative Health Law, Europe, Living Donation, Minors, Transplant Regulation
I. INTRODUCTION AND BACKGROUND

Living donation is a life-saving treatment option for patients suffering from end-stage organ failure or diseases such as leukaemia, lymphoma and sickle cell anaemia. Although, as a rule, living donation is restricted to adults, minors may also come into view. Occasionally, minors may offer the best available match for living organ or tissue transplantation, especially if they are closely related to the recipient.

Whether living donation by minors should be allowed is the subject of considerable debate. Critics warn that, from a naïve utilitarian perspective, living donation by minors may all too often appear the preferred solution.¹ This may in particular be the case where siblings are concerned, because they offer close donor matches, are easily accessible and allow the recipient to avoid transplant waitlists. The vulnerability of minors who are solicited as living donors is further exacerbated by their susceptibility to pressure or even coercion. Compared to competent adults, who have every right to decline donation even if they are the donor of last resort,² minors may find themselves in a position where they may be compelled to donate. Similar concerns are raised about the necessity of involving minors, the severity of the risks to which minors would be exposed, the compatibility with the minors’ best interests, the maturity of minors to participate in decision-making, and the impartiality of the authorisation procedure when parents have a conflict of interest. As a result, some scholars and a large

² See, for the United States, the illustrative case of McFall v Shimp (1978) 10 Pa & C 3d 90.
majority of guidelines, position papers and reports that more specifically focus on living organ donation by minors endorse a complete ban.³

By contrast, proponents of living donation by minors argue that an absolute prohibition would also be morally problematic. They emphasise that categorically refusing minors the possibility to donate may amount to unfair treatment because it would uniformly disregard a genuine willingness to donate.⁴ Similarly, it is pointed out that living donation may exceptionally be in the best interests of minors.⁵ This would be the case where the psychological benefits to the minor would outweigh the risks associated with the intervention. Primary psychological benefits that have been identified in this regard include prevention of severe psychological distress that would be caused by the loss of a loved one, avoidance of guilt feelings when the minor grows up, continuation of the personal relationship with the recipient, and the positive feelings that might flow from the altruistic act itself. The consideration that living donation by minors may exceptionally be in their best interests has prompted several commentators to leave the door open for such a practice.⁶ This approach was followed by a variety of

Invariably, a whole range of protective measures are proposed to minimise the likelihood that minors would be taken advantage of. In accordance with these safeguards, living donation by minors should only be allowed as a last resort and within intimate families, and if, in addition, the risks are minimised and significantly lower than the anticipated psychological benefits to the donor. Finally, donor assent, parental permission and approval by an independent body should have been obtained.

On the basis of these considerations, living tissue and even organ donation by minors is legally allowed in several non-European countries, such as the United States, Canada and Japan. Regardless of this legal possibility, clinical practice in these countries differs markedly depending on the type of body material that is donated. Donation of bone marrow (hematopoietic stem cells) by minors, especially to their siblings, has become a relatively common procedure. Since bone marrow regenerates, the risks of complications are very small, no alternative medical treatment exists and important psychological benefits to the minor are anticipated, this kind of intervention is generally considered justifiable. By contrast, the risks of living kidney donation are more than minimal, prompting a much more cautious approach.

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8 See, for the United States, the case law in Hart v Brown, A 2d 386 (Conn Super Ct 1972); In re Richardson, 284 So 2d 185 (La Ct App 1973); Little v Little [1979] 576 SW 2d 493 (Tex Ct of App) and Curran v Bosze, 566 NE 2d 1319 (Ill 1990).

Cases of living kidney donation by minors have been recorded in the United States, Canada, Japan, South Korea and Brazil. Since the risks involved in living donation of other organs are very significant, minors are as a rule excluded. However, rare cases of living donation of a liver segment by a minor have been reported in the United States, Japan and Brazil.

Having taken into account the situation in these non-European countries, the question remains as to what approach is taken in Europe. To this aim, this article will examine how tissue and organ donation by minors is regulated in the 28 EU Member States, Norway and Switzerland.

II. LIVING ORGAN AND TISSUE DONATION BY MINORS IN INTERNATIONAL INSTRUMENTS


14 Currently, the European Union comprises 28 Member States: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and United Kingdom.
Before examining the national regulations on living organ and tissue donation by minors, we will analyse how minors are protected in international legal instruments and transplantation guidelines.

A. International Standards for the Protection of Minors

The need to extend particular protection to minors was first articulated in the Geneva Declaration of the Rights of the Child, adopted by the League of Nations in 1924. At the level of the United Nations, it was affirmed by the General Assembly in the Universal Declaration of Human Rights (1948), the Declaration of the Rights of the Child (1959), the International Covenant on Civil and Political Rights (1966) and the International Covenant on Economic, Social and Cultural Rights (1966).  

The Convention on the Rights of the Child, adopted by the General Assembly in November 1989 and entered into force in September 1990, is the first international legal instrument to give the rights of minors binding legal force and to develop international standards for their protection. The Convention makes reference to ‘children’, defined as a person under the age of eighteen years, unless under domestic law majority is attained earlier. It states, in Article 3, that, in all actions affecting children, their best interests must be a primary consideration and, in Article 12, that their views, when they are capable of forming them, should be given due weight in accordance with their age and maturity. Both principles are reiterated in the World Declaration on the Survival, Protection and Development of Children, adopted at the United Nations World Summit for Children on 30 September 1990, the Vienna Declaration, adopted.

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Within the framework of the Council of Europe, no binding legal instrument has currently been adopted which develops protective standards for minors, although their rights in proceedings before a judicial authority are laid down in the European Convention on the Exercise of Children’s Rights, adopted in 1996, and their general social rights are elaborated in the European Social Charter, adopted in 1961 and revised in 1996.\(^\text{18}\) However, Recommendation CM/Rec(2012)2 on the participation of children and young people under the age of 18, adopted by the Council of Europe Committee of Ministers in March 2012, contains extensive non-binding provisions.\(^\text{19}\) It recommends that the governments of the Member States ‘ensure that all children can exercise their right to be heard, to be taken seriously and to participate in decision making in all matters affecting them, their views being given due weight in accordance with their age and maturity.’ In addition, the Recommendation elaborates on this principle by stipulating that minors, as they acquire more capacities, should be encouraged to enjoy, to an increasing degree, their right to influence matters affecting them. In order to be able to participate meaningfully and genuinely, they should be provided with all relevant information and offered adequate support appropriate to their age and circumstances. Minors should also be fully informed of the scope and the limitations of their participation and how their views were ultimately considered.

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At the level of the European Union, the principle that in all actions relating to minors, their best interests must be a primary consideration and their views must be taken into consideration in accordance with their age and maturity, is enshrined in Article 24 of the Charter of Fundamental Rights of the European Union, solemnly proclaimed by the European Parliament on 7 December 2000 but entered into force only on 1 December 2009.\textsuperscript{20} The idea that minors are entitled to special measures of protection and to effective participation in decision-making is asserted in the EU Guidelines for the Promotion and Protection of the Rights of the Child, adopted in 2007 and spelling out the principles which the EU should observe in its external human rights policy.\textsuperscript{21}

\textbf{B. International Guidelines on Transplantation}

Numerous international organisations have enacted guidelines for living organ and tissue donation. In May 1991, the World Health Assembly endorsed several Guiding Principles on Human Tissue, Cell, and Organ Transplantation, which were last revised in May 2010.\textsuperscript{22} Guiding principle 4 stipulates that no cells, tissues or organs should be removed from the body of a living minor for the purpose of transplantation. However, narrow exceptions may still be allowed under domestic law. In this regard, the commentary to the guiding principle hints at the possibility of donation of regenerative cells to a family member when no adult donor is available and to kidney transplants between identical twins. The guiding principle further requires that, where domestic legislation would indeed allow living donation by a minor, specific protective measures should be put in place and, wherever possible, the assent of the minor should be obtained before donation.


The World Medical Association’s Statement on Human Organ Donation and Transplantation, adopted in October 2000 and revised in October 2006, states that minors should not be considered as potential living donors, except in extraordinary circumstances and in accordance with established protocols or a review by an ethics committee.\(^{23}\) In its Statement on Organ and Tissue Donation, adopted in October 2012, the World Medical Association reaffirmed the principle that persons who are unable to consent should not be considered as living organ donors, because they lack the capacity to understand and decide voluntarily. However, exceptions may be allowed in very limited circumstances and following legal and ethical review.\(^{24}\)

In 2004, the Ethics Committee of the Transplantation Society issued its Consensus Statement of the Amsterdam Forum on the Care of the Live Kidney Donor, emphasising that minors should not be used as living kidney donors.\(^{25}\) In 2006, the same Committee issued its Ethics Statement of the Vancouver Forum on the Live Lung, Liver, Pancreas, and Intestine Donor.\(^{26}\) This Statement underlines that persons who are legally incompetent or who lack the capacity for autonomous decision-making should not be considered as living lung, liver, pancreas or intestine donors. Rather surprisingly, however, it allows that in rare instances exceptions may be made, requiring that, the case being, an independent donor advocate must be appointed.

\section*{C. International Binding Legal Instruments on Transplantation}


Although these transplant guidelines exert considerable influence on the national legislation of the EU Member States, Norway and Switzerland, they are not directly binding and, consequently, may be disregarded. By contrast, the European Union and the Council of Europe have adopted binding legal instruments in the domain of transplantation.

At the level of the European Union, the most important legal instruments addressing organ and tissue donation are Directive 2004/23/EC on Setting Standards of Quality and Safety for the Donation, Procurement, Testing, Processing, Preservation, Storage and Distribution of Human Tissues and Cells, adopted by the European Parliament on 31 March 2004, and Directive 2010/53/EU on Standards of Quality and Safety of Human Organs Intended for Transplantation, adopted on 7 July 2010.27 Although their primary objective is to establish an effective framework for the quality and safety of human organs, tissues and cells, they contain some principles on living organ donation. However, since human rights considerations in this field fall outside the remit of the European Union, provisions relevant to donation by minors are very general. Directive 2004/23/EC states, in Article 13, that human tissues and cells may only be procured “after all mandatory consent or authorisation requirements in force in the Member State concerned have been met”. Similarly, Directive 2010/53/EU stipulates, in Article 14, that the procurement of an organ from a living person is only allowed “after all requirements relating to consent or authorisation, in force in the Member State concerned, have been met”. Consequently, both Directives leave it to the Member States to decide whether minors should be allowed to donate tissues and/or organs.

By contrast, the Council of Europe offers specific guidance on the topic of living donation by minors. The Convention on Human Rights and Biomedicine, adopted on 4 April 1997 and entered into force on 1 December 1999, and its Additional Protocol on Transplantation of Organs and Tissues of Human Origin, adopted on 24 January 2002 and entered into force on 1 May 2006, contain detailed provisions on organ and tissue procurement from minors.\(^{28}\) Article 6, paragraph 1, of the Convention only allows a medical intervention on persons who do not have the capacity to consent if it is in their direct benefit. As a consequence, the removal of organs and tissues from persons who lack the legal ability to consent is prohibited. To remove all doubt, this cardinal principle is made explicit in Article 20, paragraph 1 of the Convention. However, exceptionally and under the protective conditions prescribed by domestic law, Article 20, paragraph 2, permits removal of regenerative tissue provided that several conditions are met: (1) no compatible donor is available who has the capacity to consent, (2) the recipient is a sibling of the donor, (3) the donation has the potential to be life-saving, (4) the representative or authority, person or body provided for by law has given free and informed, specific and written authorisation, in accordance with domestic law and approved by a competent body\(^{29}\), and (5) the potential donor does not object.

In addition, Article 6, paragraph 2, specifies that the opinion of minors, who do not have the capacity to consent, have to be taken into consideration as an increasingly determining factor


\(^{29}\) The Explanatory Report to the Convention on Human Rights and Biomedicine clarifies, in paragraph 129, that such a body might be a court, a professionally qualified body, an ethics committee, etc. The Explanatory Report is available at http://conventions.coe.int/treaty/en/Reports/Html/164.htm.
in proportion to their age and degree of maturity. Finally, Article 6, paragraph 5, provides that the authorisation provided on behalf of the minor may be withdrawn at any time in the best interests of that person. This implies that, as set out in the international standards for the protection of minors, the best interests of the minors must be a primary consideration when deciding whether or not to authorise organ or tissue removal. All these provisions are reiterated in the Additional Protocol. During the revision of the Additional Protocol in June 2012, a new paragraph was introduced in its Explanatory Report, clarifying that the capacity to consent is understood in relation to a specific type of intervention and is defined by domestic law. Consequently, where under domestic law minors from a certain age are accorded the capacity to consent to living organ and/or tissue donation, these restrictions do not apply to them.  

III. LIVING ORGAN AND TISSUE DONATION BY MINORS

IN DOMESTIC REGULATIONS

A. General Considerations

We will now examine how living tissue and organ donation by minors is regulated in EU Member States, Norway and Switzerland. Before proceeding, it should be noted that at the national level living donation of tissues and organs may be governed by a wide variety of statutory and non-statutory instruments. Living donation is typically regulated by parliamentary acts which are supplemented by executive degrees. Frequently, additional guidance on living tissue and organ donation is offered by codes of practice or ethical

31 For their invaluable assistance with the legal analysis of domestic transplant regulations, we would like to thank the following legal experts: Jasper Bovenberg (The Netherlands), Giovanni Comandé (Italy), Horatiu Crisan (Romania), Bianka Dörr (Switzerland), Anne-Marie Duguet (France), Jaunius Gumbis (Lithuania), Thomas Gutmann (Germany), Mette Hartlev (Denmark), Louiza Kalokairinou (Greece/Cyprus), Graeme Laurie (Scotland), Herman Nys (Belgium), Shaun Pattinson (England/Wales), André Pereira (Portugal), Mayte Requejo Naveros (Spain), Dula Rusinovic-Sunara ( Croatia), Mike Schwebag (Luxembourg), Sirpa Soini (Finland) and Karl Harald Søvig (Norway).
guidelines issued by national health or transplant authorities, professional associations or ethics committees.

In Ireland and Malta no legal instruments setting out the requirements for living tissue and organ donation have currently been adopted, whereas in Austria living tissue donation currently is not covered in a transplant act. In all other countries under consideration, the requirements for living tissue and organ donation are regulated in a legal instrument. In Denmark, France, Hungary, Romania and Slovakia, provisions are included in the Health Code. By contrast, in Bulgaria, Cyprus, Czech Republic, Estonia, Finland, Germany, Latvia, Lithuania, The Netherlands, Norway, Poland, Portugal, Slovenia, Sweden, Switzerland and United Kingdom, the requirements for living tissue and organ donation are governed in one act. Belgium, Croatia, Greece, Italy, Luxembourg and Spain have instead opted to cover living donation of tissues and organs in two separate acts. In most of these countries, legislators have opted to incorporate the provisions of EU Directives 2004/23/EC and 2010/53/EU directly in the national transplant act(s). However, some countries, such as the United Kingdom, deal with the quality and safety aspects of tissues and organs in distinct legal instruments.

The analysis of the domestic regulatory framework is complicated by the uneven ratification of the Council of Europe Convention on Human Rights and Biomedicine and its Additional Protocol on Transplantation of Organs and Tissues of Human Origin. To this day, the Convention has been ratified by 29 Council of Europe Member States, including 17 EU 32 A list of national measures, transposing Directives 2004/23/EC and 2010/53/EU, can be found at http://eur-lex.europa.eu/search.html?type=advanced&qid=1398439574138&or0=DN%3D72004L0023*, respectively http://eur-lex.europa.eu/search.html?type=advanced&qid=1398439574138&or0=DN%3D72010L0053*.
Member States, Norway and Switzerland. Only 12 of the aforementioned Council of Europe Member States have also ratified the Additional Protocol. These include six Member States of the European Union and Switzerland.

In ratifying countries, the provisions of the Convention and, the case being, those of the Additional Protocol are to be given effect as national regulation. Provisions have to be incorporated into internal law, either by adapting existing legislation or by enacting new legislation. However, even where provisions have not been formally transposed, they may qualify as directly binding. In accordance with the constitutional principle of priority of treaty law over domestic law or, in the absence of such constitutional clause, consistent with national and European jurisprudence and legal doctrine, provisions with a so-called self-executing character will have direct effect, over and above those provided for in national law.

Provisions are self-executing when they do not merely impose obligations to the state but also confer unconditional, clear and precise rights to citizens. In this regard, the restrictions placed by the Convention and its Additional Protocol on the removal of tissues and organs from minors are to be considered as directly binding. This observation is particularly relevant for ratifying states which have not in detail regulated living donation by minors, such as Denmark and Latvia.

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33 EU Member States that have ratified the Convention on Human Rights and Biomedicine are Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Latvia, Lithuania, Portugal, Romania, Slovakia, Slovenia and Spain. An up-to-date list of ratifications can be consulted at http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=164&CM=8&DF=18/02/2012&CL=ENG.

34 EU Member States that have ratified the Additional Protocol on Transplantation of Organs and Tissues of Human Origin are Bulgaria, Croatia, Estonia, Finland, Hungary and Slovenia. An up-to-date list of ratifications can be consulted at http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=186&CM=8&DF=18/02/2012&CL=ENG.


36 See the Explanatory Report to the Convention on Human Rights and Biomedicine, paragraph 20.
However, the direct applicability of the requirements for living tissue and organ donation by minors do not need to imply that these exact conditions will apply in ratifying states. Indeed, by virtue of Article 27 of the Convention citizens may always be granted a wider measure of protection, for instance by simply prohibiting certain types of living donation by minors.\textsuperscript{37} In addition, Article 36 allows ratifying states to make a reservation in respect of a particular provision to the extent that legislation in force in its territory is not in conformity. As will be discussed, several ratifying states have indeed submitted a reservation to Article 20, paragraph 2, stating that under their legislation the donation by persons unable to consent will not be restricted to donation to siblings.

A final element which may account for differences in the national regulation of tissue and organ donation by minors concerns divergences in the legal status of minors under domestic law. In most countries under consideration persons at an age lower than the legal age of majority (i.e. typically eighteen years) are regarded as being sufficiently competent to take autonomous decisions in the health field. The exact age and circumstances under which minors are allowed to consent to healthcare procedures vary widely across Europe. In some countries, such as Cyprus, Greece and Slovakia, the age limit is the same as the legal age of majority, meaning that minors are denied the capacity to consent. Other countries define a fixed age limit above which minors are presumed to have competence. This limit may vary considerably, with some countries, such as Latvia, opting for a cut-off age of 14, while other countries, such as Denmark, prefer the age of 15, and still others, such as Spain, fix the age at 16. By contrast, some countries, such as Belgium, Czech Republic, Estonia and Germany opt for a more flexible approach whereby the capacity to consent has to be assessed on a case-by-case basis, depending on the minor’s ability to fully understand what the healthcare procedure

\textsuperscript{37} Ibid, paragraphs 161-162.
involves. Finally, some countries, such as Lithuania and the United Kingdom, define a fixed age limit, being 16 years, but also allow autonomous decision-making by minors below that age who demonstrate sufficient cognitive faculties.\textsuperscript{38}

In this respect, however, it should be noted that laws or jurisprudence declaring competence to take healthcare decisions at an age lower than majority do not necessarily apply to living donation. In fact, in countries where competence is presumed at a certain age of childhood, this is often restricted to decisions on the medical treatment of the minor. Similarly, where competence is determined on the basis of a case-by-case assessment, the level of maturity required from the minor depends on the level of difficulty involved in the healthcare decision. Consequently, procedures entailing serious risks will require cognitive abilities which are not easily to be found in minors. As will be discussed below, only in very few countries minors of a certain age or level of understanding are deemed to be potentially sufficiently competent to consent to living organ donation. By contrast, in many countries these minors may validly consent to living tissue donation. Frequently, transplant laws contain provisions specifying at what age, if any, minors may validly consent to living donation of tissues or even organs.

\textit{B. Countries that Only Allow Tissue Donation by Minors}

In all countries under consideration living tissue donation by minors is allowed. Where the requirements for living donation are regulated in a legal instrument, provisions specify that minors may be considered as potential donors of bone marrow. In Ireland, pending the adoption of the Human Tissue Bill, this possibility is provided by ethical guidelines. By contrast, in countries where no legal framework or ethical guidelines for tissue donation currently exist, such as Austria and Malta, the situation is more uncertain. According to legal

doctrine, tissue donation by minors will likely be allowed under the general principles on the protection of minors, as long as it can be presumed that it will be in the minor donor’s best interests to save the life of the recipient.\textsuperscript{39}

In all but six of the 30 countries considered living organ donation by minors is resolutely prohibited. This is the case for Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Switzerland. With the exception of Austria, Germany, Italy, Malta, The Netherlands, all of these countries have ratified the Convention on Human Rights and Biomedicine. Most of the ratifying states have amended their transplant regulation to be in line with the Convention. In ratifying states that failed to amend their transplant law accordingly, such as Denmark and Latvia, the requirements set out in the Convention will still be applicable due to their self-executing nature.

Interestingly, even in those non-ratifying states where minors are only allowed to donate tissues, the restrictions placed by the Convention seem to be largely respected. In Germany and The Netherlands, the transplant law closely resembles the provisions of the Convention in this regard. In Italy, legislation does not contain detailed provisions on living tissue donation by minors and, consequently, does at first sight not seem to be in line with the Convention. However, since the applicable legislation predates the adoption of the Convention and Italy is considered a non-ratifying state only because it chose not to submit its 2001 ratification instrument to the Council of Europe, we can readily assume general agreement with its

provisions. As to Austria and Malta, in the absence of a legal framework and ethical guidelines, the best interests of the minor will be the central criterion. Legal doctrine indicates that in extraordinary circumstances, such as those defined in the Convention, living tissue donation may be in the minor’s best interests. Clearly, the Convention is considered as a standard-setting instrument even in non-ratifying states, with considerable interpretative impact or even resulting in transplant regulations being drafted along the same lines.

In sum, in countries where minors are only allowed to donate tissue, requirements are very similar and in conformity with the conditions set out in the Convention on Human Rights and Biomedicine and reiterated in its Additional Protocol concerning Transplantation. In these countries, living tissue donation by minors will only be allowed if, in addition to the requirements applicable to living tissue donation by adults, five protective conditions are fulfilled.

First, minors may only be considered as living tissue donors in the absence of a compatible donor who is able to consent. As clarified in the Explanatory Memorandum to the Convention, this implies that ‘within reasonable limits’ efforts need to be undertaken to find a competent compatible donor.\(^{40}\) In the same vein, the French transplant regulation specifies that every effort should first have been made to find an adult donor who is sufficiently compatible.

Second, the envisaged donation must have the potential to save the life of the intended recipient. This condition is dictated by the consideration that a reasonable benefit-to-risk ratio should be guaranteed since, unlike competent donors, minors do not have the capacity to

\(^{40}\) Explanatory Report to the Convention on Human Rights and Biomedicine, paragraph 126.
autonomously decide what benefit-to-risk balance would be acceptable. In practice, this means that living tissue donation by a minor may only come into view as a therapy of last resort for a person who is in mortal danger. Furthermore, the health risks to the donor should be reasonable. Although this condition also holds for competent donors, the Explanatory Memorandum hints that, where minors are considered, the maximum threshold of anticipated risk will have to be considerably lower to be acceptable.\footnote{Ibid, paragraph 127.}

Third, minors should only be considered to donate tissue when the intended recipient is a close relative. This restriction is prompted by the concern that the procedure should be in the minor’s best interest and, consequently, should be to that person’s psychological benefit. This requirement can be inferred from Article 6, paragraph 5 of the Convention and is made explicit in the Explanatory Memorandum to the Additional Protocol, indicating that an exception to the prohibition of tissue removal can be justified by “the principle of mutual aid between very close members of a family and the possibility for psychological benefits to the donor arising from donation”.\footnote{Explanatory Report to the Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin, paragraph 83.} According to this line of reasoning, minors are allowed to donate only when it can be assumed that their own interests would be severely compromised by the death of a person with whom they are emotionally intimate and in a position to save. The Dutch transplant law makes this explicit, by stating that minors who are unable to consent are only allowed to donate tissue if they have a keen interest in averting the mortal danger of the intended recipient.

As to the nature of the acceptable relationship between the minor donor and the recipient, considerable variation exists. In line with the Convention, all countries allow living tissue donation by a minor for the benefit of a sibling. Some countries that have not ratified the
Convention have broadened the acceptable categories of recipients. For instance, in Germany and The Netherlands, minors may also donate to a parent or, when they are parents themselves, to a child. By contrast, several ratifying states keep to the restriction to recipients who are siblings. However, some ratifying states have submitted a reservation to Article 20, paragraph 2, stating that donation will not be restricted to siblings. For instance, Croatia and Denmark also allow living tissue donation by minors when the recipient is a parent, Switzerland when the recipient is a parent or child and France when the recipient is a first cousin, uncle, aunt, nephew or niece.\(^43\)

Surprisingly, several countries that have ratified the Convention and that did not make a reservation to Article 20, paragraph 2, have also opted to extend the possibility of living tissue donation to recipients other than siblings. In Bulgaria, such donation is allowed also when the recipient is a parent, child or spouse, in Cyprus when the recipient is a relative up to the third degree, in Estonia when the recipient is a descendant, spouse or de facto spouse, parent, grandparent or their descendant, in Finland when the recipient is a close family member or other close person, in Lithuania when the recipient is a parent, a foster parent or a biological child of a foster parent and in Romania when the recipient is a relative up to the fourth degree. Although donation to parents and children may possibly be regarded as still in compliance with the spirit of the Convention, because they are relatives of a closer degree of consanguinity than siblings, allowing donation to more distant relatives will presumably give rise to a conflict of law.

Fourth, minors are only allowed to donate tissue after all consent or authorisation requirements in force in the country concerned have been met. As already indicated, in some

countries minors above a fixed age limit are presumed to have the capacity to consent to healthcare procedures or, alternatively, they may on a case-by-case basis be considered to be competent to do so. However, only very few countries have extended this approach to the context of living tissue donation. As a rule, whether and, if so, under what conditions minors may validly consent to living tissue donation is specified in the domestic transplant regulations. For instance, in Denmark and Slovenia the fixed age limit defined in the Health Act also applies to the transplant law. Consequently, consent for living tissue donation will need to be obtained from minors above the age of 15. Other countries have established a lower cut-off age for consent, which, rather surprisingly, sometimes is even below the age limit required to consent to medical treatment. For instance, in Poland minors aged 13 years and older will have to give their consent before procurement may take place. Similarly, in Greece and The Netherlands this age limit has been set at 12 and in Romania even at 10. Alternatively, in some countries a case-to-case assessment of the maturity of the minor will need to be performed. For instance, in Germany and Switzerland, the consent of the minor will need to be obtained if that person is considered able to recognise the nature, significance and consequences of the donation and to express his or her will.

Technically, minors who are able to consent are not subject to the requirements for living donation by persons unable to consent as laid down in the Convention. However, the regulations in all of the 24 countries under consideration make the same conditions applicable to all minors regardless of their ability to consent. Consequently, minors who are able to consent to living tissue donation are also subject to the requirements which the Convention has specified for persons unable to consent, with the only exception that their own consent will also be needed. In practice the situation of all minors is analogous, more particularly because even in countries where some minors are deemed to be competent to consent, they
don’t have the power to autonomously decide to donate tissue. Regardless of the minor’s own competence, parental authorisation will always be required.

In addition to the consent of the competent minor and parental authorisation, final approval by an independent competent body is also mandatory. In some countries, such as Croatia, the Czech Republic, Hungary, Slovakia and Romania, permission has to be obtained from a pluridisciplinary living donor committee at the level of the transplant hospital. In other countries, such as Estonia, France, Germany, Greece, The Netherlands, Poland and Switzerland, final decision-making authority is delegated to a judge. In still other countries, including Bulgaria, Cyprus, Finland, Portugal and Slovenia, a professional body at the national level will need to be petitioned.

Fifth, tissue removal from a minor may not be carried out if that persons objects. Where minors are competent to consent, their refusal to do so will be decisive. When they have expressed consent, they may freely withdraw it at any time. Minors who according to domestic transplant regulations are not competent to consent should as far as possible be consulted. They should receive appropriate and tailored information about the nature, purpose and consequences of donation and their opinion should be obtained. As indicated in the Explanatory Memorandum to the Convention, if they express opposition, in whatever form, this must be observed. In several of the countries under consideration, transplant regulations do not explicitly state that an objection from a minor who is unable to consent will preclude living tissue donation. However, as prescribed by international standards for the protection of minors and Article 6, paragraph 2, of the Convention, their indication of refusal will have to

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44 In Switzerland it is up to each canton to establish the independent body. The power to grant final approval has in most cantons been delegated to the civil court but some cantons have instead entrusted the Guardianship Supervisory Authority. We would like to thank Dr. Bianka Dörr (Senior lecturer in Private Law at the University of Zurich) for providing this information.

45 Explanatory Report to the Convention on Human Rights and Biomedicine, paragraph 130.
be taken into consideration as an increasingly determining factor in proportion to their age and degree of maturity. It will be the task of the independent competent body to assess whether possible resistance on the part of the person concerned qualifies as an objection that would rule out tissue removal.

C. Countries that Allow Tissue and Organ Donation by Minors

Removal of an organ from a minor is allowed in six European countries only. This is the case for Belgium, Ireland, Luxembourg, Norway, Sweden and the United Kingdom.

1. Norway

In Norway, living tissue and organ donation by minors is regulated by the Transplant Law of 1973. A new transplant law is currently being debated but no major changes to the provisions on the requirements for living donation are envisaged. The Transplant Law differentiates between minors younger than 12 and minors who are 12 years and older. Minors who have not yet reached the age of 12 are only allowed to donate tissue. In line with the Convention, which has been ratified by Norway, several cumulative requirements need to be fulfilled before living tissue donation by a minor of that age may be considered. Tissue donation is only allowed if no suitable organ from a competent person is available, if transplantation is assumed to be necessary to save the life of the intended recipient, if the person with parental custody of the minor approves, and if there is no indication that the intervention would be against the will of the minor. In addition, the intervention is subject to authorisation by the County Medical Officer who should decide on the basis of the minor’s best interests. Tissue donation is allowed for the benefit of a sibling, a child or a parent or, in special cases, another
close relative of the minor. What would constitute a special case has to be considered in the light of the closeness of the relationship with the recipient and the urgency of the procedure.\textsuperscript{46} To be in line with the Convention, Norway has submitted a reservation to Article 20, paragraph 2, stating that living tissue donation by minors who are unable to consent would under its transplant law not be restricted to siblings.

Minors 12 years and older are allowed to donate tissues and organs if they are capable of understanding the nature, significance and consequences of the donation and consent in writing.\textsuperscript{47} By limiting organ donation to minors with the capacity to consent, the Norwegian transplant law is still in conformity with the Convention. Consent may only be granted “when special circumstances so warrant” and requires the approval of the person with parental custody of the minor and final authorisation by the County Medical Officer. Whether “special circumstances” exist depends on the urgency of the donation, the closeness of the relationship with the intended recipient and the intrusiveness of the surgical procedure. As indicated in the preparatory works, the reason to allow organ donation by mature minors is to permit them to help a close family member where the interdiction to donate would put them under a severe mental strain.\textsuperscript{48} The law sets no limits on who could receive tissues or organs from a mature minor. However, in practice only donation to recipients who are relatives or close friends would be accepted.\textsuperscript{49} Nonetheless, no case of living organ donation by a mature minor has yet been reported in Norway.\textsuperscript{50}

\textsuperscript{47} Lov 1973-02-09 nr 06 om transplantasjon, sykehusobduksjon og avgivelse av lik m.m., § 1.
\textsuperscript{49} Ibid, 100.
\textsuperscript{50} Ibid, 95.
2. Sweden

In Sweden, living tissue and organ donation by minors is regulated by the 1995 Transplant Law. Living donation by minors is only allowed if the minor is related to the intended recipient and if no compatible competent adult donor has been found. Regardless of their age or cognitive faculties minors are not considered competent to consent to living donation. Therefore, such procedure may only be performed on the basis of an authorisation by the parents or guardian and if the minor does not object. In addition, the Law also requires final approval by the National Board of Health and Welfare, which may grant permission only if the intervention has been endorsed by the donor’s transplant surgeon. It is not necessary that the envisaged donation has the potential to save the life of the intended recipient. However, living organ donation should only be approved “if exceptional reasons make it appropriate”\(^5\). In this regard, guidelines issued by the National Board of Health and Welfare clarify that serious danger to the recipient’s life or health may constitute an exceptional reason\(^6\). Considering that the National Board has to decide on the basis of the minor’s best interests, it may be presumed that it will only permit living organ donation as a last resort to save the life of a close relative. Up until now no case of living organ donation by a minor has been reported.

3. Belgium

In Belgium, living donation is regulated by the Law on the Removal and Transplantation of Organs, enacted in 1986. With the adoption of the Biobank Law in 2008, tissue donation was excluded from the scope of the Transplant Law, although it lasted until 2012 before the latter

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\(^5\) Lag om transplantation m.m. 8 juni 1995, § 8.

instrument was amended accordingly. Restricting the scope of the Transplant Law to the donation of organs had major consequences. Before, the Transplant Law stipulated that living organ and tissue donation by minors was allowed where this normally could not have severe consequences, involved regenerative organs and tissues only and would benefit a sibling. From minors 12 years and older prior consent was needed. Minors who had not yet attained the age of 12 had to be given the opportunity to express their opinion. Parental authorisation and, the case being, consent from the mature minor, had to be given in writing and in the presence of an adult witness whose signature was also required. The consent form had to be presented to the transplant surgeon who was only allowed to proceed after a pluridisciplinary committee at the level of the transplant hospital had given approval.

After the restriction of the scope of the Transplant Law, the provisions on living donation by minors remain largely the same but now only apply to organs.53 By removing tissues from the scope of the Law, the possibility for minors to donate regenerative tissues or organs, which had previously been interpreted as pertaining only to bone marrow and hematopoietic stem cells, was reinterpreted to only refer to liver segments or lobes. This interpretation is not in line with the approach taken in the Dutch Transplant Law, which bears close resemblance to the Belgian Transplant Law and also allows the donation of ‘regenerative organs’ by minors with specific conditions applicable depending on whether they have reached the age of 12. However, as indicated by the parliamentary proceedings which led to the adoption of the Dutch Transplant Law in 1996, ‘regenerative organs’ are to be understood as referring to bone marrow only. In accordance with the state of medical science at the time, liver donation was

explicitly excluded as far as minors were concerned. This interpretation of the Dutch Transplant Law still holds, since, unlike in Belgium, the scope of the Law was not changed and organs are still defined in a way that also encompasses tissue.

By contrast, since 2008 the provisions in the Belgian Transplant Law concerning living donation by minors are deemed applicable only to the donation of a liver lobe or segment. Parliamentary proceedings demonstrate that Belgian legislators explicitly had the donation of a liver lobe or segment in mind and were of the opinion that medical developments in the field indicated that this type of donation entailed risks which had become acceptable to allow donation by minors. Admitting that the risks were not negligible, it was deemed inappropriate to allow minors younger than 12 to donate a liver lobe or segment. Consequently, the requirements for living organ donation were slightly amended so as to only allow donation by minors 12 years or older who are capable of expressing their will and have given prior consent. However, it should be noted that contrary to legislative opinion, the majority of Belgian legal doctrine thinks that the risks involved in liver lobe or segment donation are still too high to allow the involvement of minors. Notwithstanding the on-going

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54 Tweede Kamer der Staten-Generaal (1992-1993). 22 358 Regelen omtrent het ter beschikking stellen van organen (Wet op de orgaandonatie). Nr. 5 Memorie van antwoord, 22-23, available at http://resourcesgdkb.nl/SGD/19921993/PDF/SGD_19921993_0003023.pdf. Interestingly, the responsible minister stated that the liver is not even to be considered a regenerative organ.

55 That regenerative organs are excluded can also be inferred from the fact that The Netherlands signed (although not ratified) the Convention on Human Rights and Biomedicine shortly after adopting the Transplant Law. Furthermore, in legal cases involving living donation by minors only bone marrow donation has been authorised. See in this regard, an overview of cases (in Dutch) at http://uitspraken.rechtspraak.nl/#lijn/BX9406. Finally, Dutch legal doctrine also indicates that under the Transplant Law living liver donation by minors would not be allowed. See, for instance, M Biesaart, ‘Wet op de orgaandonatie’ in B Sluijters, M Biesaart, G de Groot and L Kalkman-Bogerd (eds), Gezondheidsrecht: Tekst en commentaar (Kluwer: Deventer, 2008) 1287. However, a dissenting opinion is to be found in W Duijst, Gezondheidsrecht en strafrecht (Kluwer: Deventer, 2009) 62.


57 Ibid, 26-27.

58 See, for instance, the opinion of the Belgian Advisory Committee on Bioethics. Advies nr. 50 van 9 mei 2011 betreffende bepaalde ethische aspecten van de wijzigingen door de wet van 25 februari 2007 aangebracht aan de wet van 13 juni 1986 betreffende het wegnemen en transplanteren van organen. 2011.
debate, no case of living donation of a liver lobe or segment, or for that matter, of any other organ, by a minor has yet been reported in Belgium.

With the adoption of the Biobank Law in 2008, the conditions for living tissue donation by minors were considerably relaxed as compared to its regulation under the Transplant Law.\(^5^9\) Henceforth, it is no longer required that donation would have to benefit a sibling. In fact, no restriction of acceptable categories of recipients has been retained, with minors in theory being allowed to donate to total strangers. Similarly, the consent and authorisation procedure was changed drastically. Written consent needs to be obtained from minors who, in accordance with the Law on Patients’ Rights, are considered capable of a reasonable assessment of their interests. For incompetent minors parental authorisation is required. These forms have to be presented to the surgeon responsible for the removal of the bone marrow. However, compared to the previous regulation, consent no longer needs to be given in the presence of an adult witness whose signature on the consent form is required. In addition, final approval from a pluridisciplinary committee at the level of the transplant hospital is no longer needed. In sum, under Belgian law living tissue donation by minors is allowed even when a compatible adult donor is available, the recipient is a total stranger, donation does not have the potential to be life-saving, and no approval from a competent independent body is obtained. These provisions clearly do not comply with the standards laid down by the


\(^{59}\) Wet inzake het verkrijgen en het gebruik van menselijk lichaamsmateriaal met het oog op de geneeskundige toepassing op de mens of het wetenschappelijk onderzoek/Loi relative à l’obtention et à l’utilisation de matériel corporel humain destiné à des applications médicales humaines ou à des fins de recherche scientifique, Article 10, available at http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&1a=N&table_name=wet&cn=2008121944 (Dutch) and at http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&1a=F&cn=2008121944&table_name=loi (French).
Convention on Human Rights and Biomedicine and incorporated in the transplant regulations of the big majority of countries under consideration.

4. **Luxembourg**

In Luxembourg, organ donation is governed by the Law Regulating the Procurement of Substances of Human Origin of 1982. According to this Law, living organ donation by minors is allowed if they are capable of judgement and consent in writing, the organ will be transplanted into a sibling and authorisation is obtained from the parents and a pluridisciplinary committee consisting of at least three experts, including two physicians.60 No case of living organ donation by minors has been reported yet.61 As Luxembourg is preparing the ratification of the Convention on Human Rights and Biomedicine, amendments to the Law are currently being debated in parliament. As one of the major changes envisaged living organ donation by minors will be prohibited.62

Tissue donation is regulated by the Law on Human Tissues and Cells Intended for Human Applications, adopted in 2007. As compared to living tissue donation by adults, minors may only be considered if several additional requirements are fulfilled: no other therapeutic solution or compatible adult donor is available, the recipient is a sibling, written parental authorisation is obtained, the minor does not object and a pluridisciplinary committee

consisting of at least three experts, including two physicians, has granted approval. These provisions are clearly in line with the Convention.

5. ***Ireland***

In Ireland, organ and tissue donation is currently not dealt with by legislation. Statutory instruments mainly concern the establishment of a national framework for quality and safety of human organs and tissues. As a result, they contain few and only general requirements for living organ and tissue donation. With regard to tissue donation, the European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006, implementing EU Directive 2004/23/EC, states in Regulation 11, paragraph 3, that “tissues shall not be procured unless the information … has been provided … to the donor (in the case of a living adult donor) or the next of kin (in the case of a deceased donor or a person who is unable to give consent) and informed consent has been given”. Similarly, the European Union (Quality and Safety of Human Organs Intended for Transplantation) Regulations 2012, transposing EU Directive 2010/53/EU, requires in Regulation 22, paragraph 1, that “organs shall not be procured in the case of a living donor unless the donor has given informed consent to the donation or the donation is otherwise permitted by law”. Notwithstanding their general wording, these provisions already indicate that organ and tissue procurement from a person who is unable to give consent may be allowed in Ireland.

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Pending the adoption of the Human Tissue Bill, the requirements for living tissue and organ donation by minors are spelled out in ethical guidelines drafted for the Irish Living Donation Programme. Both types of donation are subject to the same set of severe restrictions. As is the case for living donation by competent adults, donation is only allowed for the therapeutic benefit of an intended recipient and if no organs or tissues from a cadaveric donor or therapeutic alternatives of comparable effectiveness are available. Several additional requirements need to be fulfilled where minors are concerned. For instance, donation may only proceed if no competent adult donor is available and if donation would entail only minimal risk and discomfort to the donor and is expected to be of great benefit to the recipient. With regard to the nature of the relationship between the donor and the recipient, it is specified that donation is only acceptable for the benefit of a recipient with whom the minor has an intimate relationship (i.e., a sibling or a parent). Other criteria focus on the decision-making procedure to be followed. In addition to parental authorisation, the assent or, where competent, the consent of the minor will need to be obtained and approval by the High Court should be sought. It is further stipulated that donation may only be authorised when all decision-makers involved are convinced that donation would be in the best interests of the minor.66

Notwithstanding these ethical guidelines, considerable uncertainty currently exists as to the legal status of mature minors. Similar to corresponding provisions in other European countries, the Non-Fatal Offences Against the Person Act 1997 allows minors who have attained the age of 16 years to consent to surgical, medical or dental treatment without requiring parental authorisation.67 In contrast to the United Kingdom, the scope of these

66 We would like to thank Dr. Sióbhan O’Sullivan (Lecturer in Healthcare Ethics and Law at the Royal College of Surgeons of Ireland, Dublin) for providing this information.
provisions has not yet been judicially considered in Ireland. With regard to intrusive procedures which might not easily be characterised as treatment, such as living tissue or organ donation, the question arises as to the limits of the mature minor’s autonomy, especially in the light of the extensive rights that under the Irish Constitution are awarded to parents. Not surprisingly, a cautionary approach has been advocated in professional guidelines, as reflected in the ethical guidelines mentioned above. Similarly, the Guide to Professional Conduct and Ethics for Registered Medical Practitioners, published by the Irish Medical Council in 2009, states that, although minors aged 16 and over are entitled to give their own consent to treatment, this entitlement does not apply to areas such as tissue or organ donation.

However, as indicated during the consultation procedure regarding the general scheme for the future Human Tissue Bill, a few submissions proposed to give due consideration to the autonomy of the mature minor even in the context of living tissue and organ donation. Consequently, although the initial scheme of the Bill did not provide for this possibility, the current version differentiates between minors depending on whether they have attained the age of 16. Minors who are younger than 16 will only be allowed to donate if the requirements applicable to competent living donors are fulfilled, there is no compatible donor who has the capacity to consent, the recipient is a sibling and the donation is potentially life-saving for the recipient. In addition, the potential donor’s assent needs to be obtained, as well as authorisation from the parents and the High Court, deciding on the basis of the best interests standard.

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68 D Madden, Medicine, Ethics and the Law (Bloomsbury Professional: Haywards Heath, 2011) 513-514.
By contrast, minors who have attained the age of 16 will, for the purposes of the Human Tissue Bill, be considered as adults, in line with the rule on mature minors laid down in the Non-Fatal Offences Against the Person Act 1997. Consequently, they will be allowed to become living donors if the donation is for the therapeutic benefit of an intended recipient, if there are no available organs or tissues from a cadaveric donor and no therapeutic alternatives of comparable effectiveness and if they have a close personal relationship with the intended recipient. Given the strong constitutional rights of the family in Ireland, the medical staff is advised to petition the High Court when the parents would object to the donation. As of now, no case of organ donation by a minor has been reported. However, a proposed kidney donation by a 12-year-old girl suffering from Down’s syndrome to her 8-year-old brother was withdrawn at the last moment when a compatible donor was found.\footnote{Communication by Dr. Sióbhan O’Sullivan.}

6. United Kingdom

In the United Kingdom, with the exception of Scotland,\footnote{In Scotland, living organ and tissue donation by minors is regulated in the Human Tissue (Scotland) Act 2006 and the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006. According to these instruments, removal of tissues is allowed if there is no competent adult who could act as a donor, the removal involves at most a minimal foreseeable risk and discomfort, and the person concerned has not indicated an unwillingness to be a donor. Where these requirements have been fulfilled, the person concerned needs to be referred to an independent Assessor and final decision-making authority is delegated to the Human Tissue Authority. Removal of an organ from a minor is allowed only as part of a domino organ transplant operation (i.e. a transplant procedure during which an organ is removed from the recipient which in turn may prove suitable for transplantation into another person). Since this form of donation is not regulated by the Human Tissue Act, the procedure is not subject to approval by the Human Tissue Authority but is instead covered by the common law. It should be noted that under Scottish legislation a person becomes an adult when they reach the age of 16. See Human Tissue (Scotland) Act 2006, available at www.opsi.gov.uk/legislation/scotland/acts2006/asp_20060004_en_3#pt1-pb3; Human Organ and Tissue Live Transplants (Scotland) Regulations 2006, available at www.oqps.gov.uk/legislation/ssi/ssi2006/ssi_20060390_en_1.} living organ and tissue donation is governed by the Human Tissue Act 2004. According to the Act, the removal or use of ‘transplantable material’ from a living person for the purposes of transplantation is only allowed when the conditions as specified in the Regulations issued by the Secretary of State...
are complied with and the Human Tissue Authority is satisfied that these conditions are fulfilled.\textsuperscript{73} The relevant Regulations are the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, which define ‘transplantable material’ as an organ or part of an organ and, as far as incompetent persons are concerned, also bone marrow and peripheral blood stem cells.\textsuperscript{74}

When living donation by an incompetent minor is considered, the matter should be referred to the Human Tissue Authority by a medical practitioner who has clinical responsibility for the donor.\textsuperscript{75} The Authority’s decision has to be made by a Transplant Approval Team in case of living bone marrow or stem cell donation and by a panel of no fewer than three members in case of living organ donation.\textsuperscript{76} The Human Tissue Authority must be satisfied that no reward has been given and that the removal is consensual or otherwise lawful.\textsuperscript{77} In reaching its decision, the Authority has to take account of a report submitted by a HTA-approved independent Assessor.\textsuperscript{78} The Assessor conducts interviews with the donor and the person who has parental responsibility, ensuring that there is no evidence of duress or coercion and that parental consent has been given freely and on the basis of complete and intelligible information.\textsuperscript{79} Although the Human Tissue Act and the Regulations do not contain additional requirements, the Human Tissue Authority has issued Codes of Practice, recommending that,

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\item \textsuperscript{73} Human Tissue Act 2004, S. 33, available at \url{http://www.legislation.gov.uk/ukpga/2004/30/pdfs/ukpga_20040030_en.pdf}. The Human Tissue Authority is an executive public body of the Department of Health, established to ensure that human tissues are used safely and ethically. It regulates the organisations involved in the removal, storage and use of tissues, approves living organ and bone marrow donation and issues Codes of Practice laying down standards for the sectors it regulates. See \url{http://www.hta.gov.uk/aboutus.cfm}.
\item \textsuperscript{75} Ibid, R. 11(2).
\item \textsuperscript{76} Ibid, R. 12(1) and (2).
\item \textsuperscript{77} Ibid, R. 11(3).
\item \textsuperscript{78} The independent Assessor is a professional attached to a hospital transplant unit with the responsibility to assess whether the requirements of the Human Tissue Act and Regulations 2006/1659 have been met.
\item \textsuperscript{79} Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, R. 11(6)-(9). The Human Tissue Act 2004, S. 2(4), clarifies that, where the child is not competent ‘appropriate consent’ means the consent of a person who has parental responsibility.
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in accordance with common law and the Children Act 1989, court approval should be obtained before organ removal and, if there is any doubt as to best interests of the minor, also before the removal of bone marrow or stem cells. Both Codes emphasise that a court ruling should be in place before the case is even referred to the Authority. The applicable court will be the Family Division of the High Court or the Court of Protection, which will have to determine whether donation would be in the best interests of the minor, by considering the ‘welfare checklist’ set out in the Children Act 1989.

When living donation by competent minors is considered the procedure may differ considerably, since they are treated as competent adults. Living donation of bone marrow or stem cells can be carried out on the basis of the free and informed consent of the competent minor, without requiring approval of the Human Tissue Authority. The person with parental responsibility does not need to give authorisation and no court approval will need to be sought. However, the Code of Practice states that it would be good practice to consult the person with parental responsibility and to involve them in the decision-making of the minor, although the decision to consent must be the minor’s alone.

The procedure to be followed for living organ donation by competent minors is similar to the one involving incompetent minors, with the exception that the consent of the person concerned will suffice. Again, donation will be subject to approval of the Human Tissue Authority Code of Practice 2 - Donation of solid organs for transplantation, paragraph 47, available at: http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code2donationoforgans.cfm; Human Tissue Authority Code of Practice 6 - Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation, paragraph 33, available at http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code6donationofbonemarrow.cfm.


Human Tissue Authority Code of Practice 6 - Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation, paragraph 75.
Authority, seized by a medical practitioner who has clinical responsibility for the donor. The Authority must be satisfied that no reward has been given and that the removal and that the competent minor has given valid consent. The independent Assessor will only need to ensure that the minor has given free and informed consent. The only difference with competent adults is that the Authority’s decision must always be made by a panel of no fewer than three members where a competent minor is concerned, whereas for competent adults a panel decision would only be required for specific types of living organ donation such as non-directed altruistic donation.\(^{84}\) Although no additional requirements are prescribed in the statutory instruments, the Code of Practice recommends that involvement of the person with parental responsibility should be sought and court approval obtained before proceeding to organ removal from a competent minor.\(^{85}\)

The Human Tissue Act itself offers no guidance as to when a minor is to be considered competent to consent to living organ or tissue donation. In fact, whether minors can be sufficiently competent to do so is a matter of considerable debate. In this context, it is important to note that the Family Law Reform Act 1969 gives minors of 16 and 17 years of age the right to consent to ‘any surgical, medical or dental treatment’, with their consent being as effective as that of an adult.\(^{86}\) However, treatment may not cover every medical procedure and it seems unlikely that tissue or organ donation can be classified as treatment.\(^{87}\) This line of reasoning inspired the Court of Appeal in Re W (A Minor) to state obiter that the Family

\(^{84}\) Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, R. 12(1), (2) & (4). R. 12(5) defines ‘non-directed altruistic donation’ as “the removal of transplantable material of transplantable material from a donor for transplant to a person who is not genetically related to the donor or known to him”. The different treatment of competent minors and competent adults results from the fact that the provisions on the procedure before the Human Tissue Authority vary depending on whether the person is a child and the Human Tissue Act defines a ‘child’ as “as a person who has not attained the age of 18 years”. See Human Tissue Act 2004, S 54(1).

\(^{85}\) Human Tissue Authority Code of Practice 2 - Donation of solid organs for transplantation, paragraphs 84-85 & Appendix A, paragraph A10.


Law Reform Act 1969 would not apply to donation because, “so far as the donor is concerned, these do not constitute either treatment or diagnosis”.\(^8^8\)

However, an alternative approach to the maturity of minors in the healthcare setting has been developed under common law. In the famous 1986 Gillick case, whereby the House of Lords followed the claim of the Department of Health and Social Security that a physician could provide contraceptive advice to a minor without consulting her parents, it was accepted that a minor who has sufficient understanding and intelligence to understand fully what is proposed can provide legal consent for a medical procedure.\(^8^9\) Since the level of maturity needed will depend on the severity of the issue in question, the applicability of the concept of Gillick competence may be limited in the context of tissue and organ donation. For instance, in the abovementioned case of Re W Lord Donaldson regarded it as highly improbable that a minor would be considered as being sufficiently competent to be able to consent to such an intrusive procedure as kidney donation.

During the Parliamentary debate of the draft Human Tissue Act and in the Explanatory Notes to the Act, it was pointed out that the capacity of the minor should indeed be determined by reference to the common law.\(^9^0\) Similarly, the Codes of Practice note that minors who can show that they are Gillick competent may consent to the proposed donation.\(^9^1\) However, as indicated, the Codes suggest a cautionary approach by recommending that, regardless of whether a minor would be considered Gillick competent, court approval should be obtained.

\(^8^8\) Re W (Minor: Medical Treatment) [1992] 4 All ER 627 (C.A.); Re W (A Minor) (Medical Treatment) [1992] 3 WLR 758 (C.A.).
\(^8^9\) Gillick v West Norfolk and Wisbech Area Health Authority [1986] AC 112.
\(^9^1\) Human Tissue Authority Code of Practice 1 - Consent, paragraph 140, available at http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm?faArea1=customwidgets.content_view_1&cit_id=652; Human Tissue Authority Code of Practice 6 - Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation, paragraphs 71-76.
A final point of contention is whether living tissue and organ donation by a minor could be in that person’s best interests if a case would come before the High Court or the Court of Protection. Since, according to the ‘welfare checklist’ of the Children Act 1989, the court should in particular have regard to the ascertainable wishes and feelings of the minor concerned, the fact that a minor who is Gillick competent consents to the procedure will weigh heavily in favour of granting approval.\(^92\) However, the situation of persons who are not Gillick competent is more uncertain. It is submitted that the donation of bone marrow or stem cells can be in the incompetent minor’s best interest, in particular when it would have the potential to save the life of a sibling or another close family member.\(^93\) This suggestion is also made in the Code of Practice, where reference is made to the emotional, psychological and social aspects of the donation of bone marrow or stem cells as compared to the very small medical risks.\(^94\) Furthermore, this line of reasoning is supported by the ruling in the case Re Y where bone marrow donation by an incompetent adult for the treatment of her sick sister was authorised on the grounds that this would be in the social and emotional interests of the incompetent.\(^95\)

However, whether organ donation could ever be in the best interests of an incompetent minor is less certain. In the case Re Y, judge Connell stated obiter that, although he had authorised bone marrow donation by the mentally incompetent person, it would be doubtful that cases involving more intrusive surgery, such as organ donation, could also be in an incompetent person’s best interests. Since, as of yet, no cases have arisen, it is unclear whether circumstances could exist in which organ donation by an incompetent minor would be

\(^{92}\) Herring (n 87) 422.
\(^{94}\) Human Tissue Authority Code of Practice 6 - Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation, paragraph 78.
\(^{95}\) Re Y (Mental Patient: Bone Marrow Donation) [1997] Fam 110.
adjudicated to be in that person’s best interests. Nevertheless, cases that have come before court in the United States suggest that this might be possible.\footnote{Hart v Brown [1972] 289 A2d 386 (Conn Super Ct); Little v Little [1979] 576 SW 2d 493 (Tex Ct App).}

IV. CONCLUDING REMARKS

An overview of the regulation on living tissue and organ donation by minors in the EU Member States, Norway and Switzerland paints a heterogeneous picture. Living tissue donation by minors seems to be allowed in all 30 countries under consideration. In 27 of them the restrictions as laid down in Article 20, paragraph 2, of the Convention on Human Rights and Biomedicine are largely respected. This is the case for Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Switzerland. Although only 19 of these countries are bound by the Convention, it is clear that its provisions have also greatly influenced the regulation in several non-ratifying states. The main differences concern the type of independent body which should be solicited to grant final approval and the types of permissible relationship between donor and recipient. With regard to the latter it was observed that several countries that have ratified the Convention on Human Rights and Biomedicine go beyond its restriction which allows donation only to sibling, without, however, having submitted a reservation in this regard. By contrast, Belgium, Sweden and the United Kingdom have opted for a different approach. The Swedish and British regulation does not contain detailed provisions but leaves it to the independent body to decide in the minor’s best interests. In Belgium, only minimal requirements are stipulated and no approval from a competent independent body even needs to be obtained.
Living organ donation by minors is currently only allowed in Belgium, Ireland, Luxembourg, Norway, Sweden and the United Kingdom, with Luxembourg preparing to abolish this possibility. By limiting organ donation to minors with the capacity to consent, the Norwegian regulation is still in conformity with the Convention on Human Rights and Biomedicine. As in Sweden, where also organ donation by incompetent minors is allowed, living donation by minors is in Norway only permitted under exceptional circumstances and subject to approval by an independent body that has to decide on the basis of the minor’s best interests. In Ireland and the United Kingdom a clear differentiation is made between competent and incompetent minors. Although competent minors are allowed to consent to living organ donation, uncertainty exists as to the need to obtain a court order and, in Ireland, parental authorisation. In Belgium, only minors 12 years or over who are capable of expressing their will are allowed to donate an organ, if they consent to the procedure and a pluridisciplinary committee at the level of the transplant hospital has given approval. Surprisingly, the Belgian law only allows these competent minors to donate a part of their liver.

We can conclude that, compared to countries such as Brazil, Canada, Japan, South Korea and the United States, the approach taken in Europe is markedly more cautious. Living organ donation by minors is only allowed in a small minority of European countries and, even where regulation is accommodating, no case of living organ donation has yet been authorised. This observation begs the question whether in the abovementioned non-European countries sufficient efforts are made to minimise the likelihood that minors would even be considered as organ donors. A useful measure that in the last decennium has become increasingly popular consists of according paediatric patients priority in the allocation of organs from deceased
donors. In this way, the probability that siblings would come into view would be greatly decreased. Ideally, this would require maximising the supply of cadaveric organs and, hence, efficient regulation of post-mortem donation. If, despite all these efforts, no suitable organ from a cadaveric donor is likely to become available, all reasonable steps need to be taken to find a donor who understands the risks and benefits of the procedure and has the capacity to consent.

On the other hand, categorically refusing to consider a minor as living organ donor even if that person would be the donor of last resort and donation would be in that person’s best interests, may fail to achieve its purpose of protection. As indicated above, in the vast majority of European countries living donation (and other non-therapeutic interventions) involving minors are only allowed if they entail no more than minimal risk, regardless of any secondary benefit. This approach may be detrimental to the person it aims to protect, if the expected psychological benefits that the minor would receive from donating are of such importance that they significantly outweigh the risks involved, even if these are more than minimal. In exceptional circumstances where the minor is the only person in a position to save the intended recipient and the minor’s own interests would be severely compromised by the death of that person, categorical refusal will be unjustifiable. It could even be argued that the approach favoured by the great majority of European countries under consideration will be in conflict with the international standards for the protection of minors and, more in particular, with the principle that in all actions relating to minors, their best interests must be a primary consideration.

Another point of contention concerns the capacity of mature minors to consent to living organ donation. Studies suggest that minors beyond the age of 14 years exhibit a level of cognitive maturity that is similar to that of adults. However, psychosocial maturity as a rule does not seem to be reached before adulthood. As a result, minors are more susceptible to social coercion, underestimate the immediate risks and long-term consequences and are more prone to impulsive behaviour. Since living organ donation requires decisions that typically elicit impulsivity and involve a high level of social coercion and considerable or even very significant risks or long-term consequences, minors will generally lack the capacity to independently consent to such an intervention. One might argue that the cognitive and psychosocial maturity of minors should be assessed on a case-by-case basis, taking into account all relevant contextual factors that may influence decision-making. In this way, adolescents who exhibit sufficient decisional capacity would not be treated differently from a competent adult donor. However, taking into account the challenges involved in assessing maturity on an individualised basis and, more particularly, the current lack of instruments to reliably do so, we propose to adopt a more cautionary approach. This would imply that in those countries where the mature minor doctrine may extend to living organ donation, the consent of the competent minor will need to be accompanied by parental authorisation and final approval by an independent body before organ removal may take place. Consequently, in all cases where living organ donation by mature minors would be considered, this should still be subject to a best interests test.


Having acknowledged that living organ donation may exceptionally be in a minor’s best interests, it should however be noted that the risk benefit calculation will only tip in favour of donation if the foreseeable risks for the donor have been found to be acceptable. This may be the case for living kidney donation but, in view of the high mortality and morbidity risks involved, generally not for living donation of a liver lobe or segment or of any other organ.\textsuperscript{101} In this light, the legal situation in Belgium does not seem to be acceptable.

Taking into account the moral considerations at stake, we suggest that the European countries that have not yet done so, amend their regulations so as to exceptionally allow living organ donation by minors, subject to a range of very stringent safeguards. These include a restriction to living kidney donation and the requirement that the minor is the donor of last resort and the transplant is absolutely necessary and will likely be successful. In addition, donation should not be allowed if the immature minor has actively dissented or, where under national law minors from a certain age are deemed competent, if the mature minor does not consent. Furthermore, parental authorisation and approval from an independent body should have been obtained, with, where possible, a prior summary judgement from a court as a welcome additional measure. Finally, these surrogate decision-makers should at all times have the best interests of the minor in mind. In practice, they should only allow donation if there is an intimate attachment between donor and recipient and if important psychological benefits to the donor are anticipated that significantly outweigh the risks involved.

\textsuperscript{101} Reference blinded for review.
### Table 1. The Regulation of Living Tissue and Organ Donation by Minors across Europe

<table>
<thead>
<tr>
<th>Country</th>
<th>Council of Europe Oviedo Convention</th>
<th>Council of Europe Additional Protocol</th>
<th>Minors</th>
<th>Organ</th>
<th>Tissue</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>-</td>
<td>-</td>
<td>---</td>
<td>?1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Belgium</td>
<td>-</td>
<td>-</td>
<td>X1,2</td>
<td>X3</td>
<td></td>
<td>1 In Austria, no legal framework or professional guidelines for tissue donation currently exist. According to Austrian legal doctrine, tissue donation by minors will be allowed under the civil code principles on the protection of minors. 2 Only minor who are 12 years or older and are able to give consent. 3 Only liver lobes may be removed; the recipient needs to be a sibling. 4 No restriction of acceptable recipient categories.</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>23.04.2003</td>
<td>30.10.2006</td>
<td>---</td>
<td>X1</td>
<td></td>
<td>1 Although Bulgaria did not make a reservation to Article 20 of the Oviedo Convention, it also allows removal where the recipient is a parent, child or spouse.</td>
</tr>
<tr>
<td>Croatia</td>
<td>28.11.2003</td>
<td>28.11.2003</td>
<td>---</td>
<td>X1</td>
<td></td>
<td>1 Croatia made a reservation to Article 20 of the Oviedo Convention, also allowing removal where the recipient is a parent.</td>
</tr>
<tr>
<td>Cyprus</td>
<td>20.03.2002</td>
<td>-</td>
<td>---</td>
<td>X1</td>
<td></td>
<td>1 Although Cyprus did not make a reservation to Article 20 of the Oviedo Convention, it also allows removal where the recipient is a relative up to the third degree.</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>22.06.2001</td>
<td>-</td>
<td>---</td>
<td>X1</td>
<td></td>
<td>1 Only where the recipient is a sibling.</td>
</tr>
<tr>
<td>Denmark</td>
<td>10.08.1999</td>
<td>-</td>
<td>---</td>
<td>X1</td>
<td></td>
<td>1 Denmark made a reservation to Article 20 of the Oviedo Convention, also allowing removal where the recipient is a parent.</td>
</tr>
<tr>
<td>Estonia</td>
<td>08.02.2002</td>
<td>17.09.2003</td>
<td>---</td>
<td>X1</td>
<td></td>
<td>1 Although Estonia did not make a reservation to Article 20 of the Oviedo Convention, it also allows removal where the recipient is a descendant, spouse or de facto spouse, parent, grandparent or their descendant.</td>
</tr>
<tr>
<td>Finland</td>
<td>30.11.2009</td>
<td>30.11.2009</td>
<td>---</td>
<td>X1</td>
<td></td>
<td>1 Although Finland did not make a reservation to Article 20 of the Oviedo Convention, it also allows removal where the recipient is a close family member or other close person.</td>
</tr>
<tr>
<td>France</td>
<td>13.12.2011</td>
<td>-</td>
<td>---</td>
<td>X1</td>
<td></td>
<td>1 France made a reservation to Article 20 of the Oviedo Convention, also, in exceptional cases, allowing removal where the recipient is a first cousin, uncle, aunt, nephew or niece.</td>
</tr>
<tr>
<td>Germany</td>
<td>-</td>
<td>-</td>
<td>---</td>
<td>X1</td>
<td></td>
<td>1 Only where the recipient is a sibling or a relative to the first degree.</td>
</tr>
<tr>
<td>Greece</td>
<td>06.10.1998</td>
<td>-</td>
<td>---</td>
<td>X1</td>
<td></td>
<td>1 Only where the recipient is a sibling.</td>
</tr>
<tr>
<td>Hungary</td>
<td>09.01.2002</td>
<td>30.11.2006</td>
<td>---</td>
<td>X1</td>
<td></td>
<td>1 Only where the recipient is a sibling.</td>
</tr>
<tr>
<td>Ireland</td>
<td>-</td>
<td>-</td>
<td>X</td>
<td>X</td>
<td></td>
<td>Pending the adoption of the Human Tissue Bill, the requirements for living tissue and organ donation are spelled out in the ethical guidelines drafted for the Irish Living Donation Programme.</td>
</tr>
<tr>
<td>Italy</td>
<td>-</td>
<td>-</td>
<td>---</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Latvia</td>
<td>25.02.2010</td>
<td>-</td>
<td>---</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lithuania</td>
<td>17.10.2002</td>
<td>-</td>
<td>---</td>
<td>X1</td>
<td></td>
<td>1 Although Lithuania did not make a reservation to Article 20 of the Oviedo Convention, it also allows removal where the recipient is a parent, a foster parent or a foster parent’s biological child.</td>
</tr>
<tr>
<td>Country</td>
<td>Date 1</td>
<td>Date 2</td>
<td>X1</td>
<td>X2</td>
<td>Note</td>
<td></td>
</tr>
<tr>
<td>--------------</td>
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<td>----------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Luxembourg</td>
<td>-</td>
<td>-</td>
<td>X1</td>
<td>X2</td>
<td>Only where the minor is capable of understanding and has agreed in writing.</td>
<td></td>
</tr>
<tr>
<td>Malta</td>
<td>-</td>
<td>-</td>
<td>X1</td>
<td>X2</td>
<td>Only where the recipient is a sibling.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>In Malta, no legal framework or professional guidelines for tissue and organ donation currently exist. However, tissue donation by minors will likely be allowed under the general principles on the protection of minors.</td>
<td></td>
</tr>
<tr>
<td>Netherlands</td>
<td>-</td>
<td>-</td>
<td>X1</td>
<td>X2</td>
<td>Only where the recipient is a sibling.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Although the Dutch transplant law allows the removal of &quot;regenerative organs&quot;, the parliamentary proceedings indicate that this is intended to refer only to bone marrow and not to liver segments.</td>
<td></td>
</tr>
<tr>
<td>Norway</td>
<td>13.10.2006</td>
<td>-</td>
<td>X1</td>
<td>X2</td>
<td>Only minors who are 12 years or older and are able to give consent.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 Only minors who are 12 years or older and are able to give consent.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2 Norway made a reservation to Article 20 of the Oviedo Convention, also allowing removal where the recipient is a child or parent, or in special cases, other close relatives.</td>
<td></td>
</tr>
<tr>
<td>Poland</td>
<td>-</td>
<td>-</td>
<td>X1</td>
<td>X2</td>
<td>Only where the recipient is a sibling.</td>
<td></td>
</tr>
<tr>
<td>Portugal</td>
<td>13.08.2001</td>
<td>-</td>
<td>X1</td>
<td>X2</td>
<td>Only where the recipient is a sibling.</td>
<td></td>
</tr>
<tr>
<td>Romania</td>
<td>24.04.2001</td>
<td>-</td>
<td>X1</td>
<td>X2</td>
<td>Only where the recipient is a sibling.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 Although Romania did not make a reservation to Article 20 of the Oviedo Convention, it also allows removal where the recipient is a relative up to the fourth degree.</td>
<td></td>
</tr>
<tr>
<td>Slovakia</td>
<td>15.01.1998</td>
<td>-</td>
<td>X1</td>
<td>X2</td>
<td>Only where the recipient is a sibling.</td>
<td></td>
</tr>
<tr>
<td>Slovenia</td>
<td>05.11.1998</td>
<td>19.01.2006</td>
<td>X1</td>
<td>X2</td>
<td>Only where the recipient is a sibling.</td>
<td></td>
</tr>
<tr>
<td>Spain</td>
<td>01.09.1999</td>
<td>-</td>
<td>X</td>
<td>X</td>
<td>Only where the recipient is a sibling.</td>
<td></td>
</tr>
<tr>
<td>Sweden</td>
<td>-</td>
<td>-</td>
<td>X</td>
<td>X</td>
<td>Only where the recipient is a sibling.</td>
<td></td>
</tr>
<tr>
<td>Switzerland</td>
<td>24.07.2008</td>
<td>10.11.2009</td>
<td>X</td>
<td>X</td>
<td>Only where the recipient is a sibling.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 Switzerland made a reservation to Article 20 of the Oviedo Convention, also allowing removal where the recipient is a parent or a child.</td>
<td></td>
</tr>
</tbody>
</table>