Deutscher Bundestag

16th legislative period

Circular 16/11781

28 January 2009

Recommendation for a decision and report

from the Committee on Health (14th Committee)

for briefing by the Federal Government
-Circular 16/11517 No A30 -

Proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation (incl. 16521/08 ADD 1 and 16521/08 ADD 2) (ADD 1 in English) COM (2008)818 final; Council Doc. 16521/O8

A. Problem

According to a survey carried out by the European Commission, there are significant discrepancies in terms of quality and safety requirements in Member States' legislation relating to organs intended for transplantation. The European Commission considers this to have repercussions on the exchange of organs between Member States. Smaller Member States consequently face a shortage of certain organs and supply problems. Furthermore, the shortage of legally available organs encourages the illegal international trade in organs.

A pilot phase initiated at the suggestion of the Conference of Community and European Affairs Committees of Parliaments of the European Union (COSAC) must serve to check whether the draft Directive is compatible with the principles of subsidiarity, before any further discussion of the content of this proposal.

B. Solution

Ascertainment of whether concerns exist concerning compliance with the Community principle of subsidiarity. This requires confirmation that Article 18 of the draft Directive does not undermine the domestic sovereignty of the Federal Republic of Germany and that the current donation-based solution is not affected. There is also a need for clarification on other specific points. A conclusive assessment of proportionality is not yet possible.

Adoption of a Resolution with the CDU/CSU, SPD and *Bündnis 90/Die Grünen* parties voting against the *Die Linke* party, with the FDP abstaining.

C. Alternatives

Rejection of the Resolution tabled by the CDU/CSU, SPD and Bündnis 90/Die Grünen parties and adoption of a motion for a Resolution by the *Die Linke* party.

D. Costs

The costs cannot be established owing to a lack of information.

Recommendation for a Decision

The Bundestag,

on the basis of the briefing by the Federal Government contained in Circular 16/11517,

is called on to adopt the following Resolution:

The Deutsche Bundestag declares:

The Deutsche Bundestag has examined the European Commission proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation - COM (2008)818 final; Council doc. 16521/08 – with respect to the choice of legal basis and the principle of subsidiarity. There are no concerns relating to the choice of legal basis. However, the Bundestag sees the need to clarify certain points in relation to compliance with the principle of subsidiarity. It is not possible to establish whether the draft Directive respects the principle proportionality, as the draft does not provide detailed information on the expected financial and administrative burdens for the Member States.

Berlin, 28 January 2009

Committee on Health

(signature) (signature)

Dr Martina Bunge Michael Hennrich

Chairwoman Rapporteur

A. General information

I. Referral

The proposal for a Directive of the European Parliament and of the Council on standards of safety and quality of human organs intended for transplantation and the Communication from the Commission: Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States, COM (2008) 818 and COM (2008) 819, Council Doc. Nos 16521/08 and 16545/08, was referred to the Committee on Health as the responsible consultative body, and to the Legal Committee and the EU Affairs Committee for their opinion.

Il Main content of the referral

The aim of the proposed Directive is to ensure that organs used for transplantation in the European Union meet uniform standards of quality and safety. The Directive should thereby facilitate the exchange of organs between Member States.

In the Member States, officially recognised responsible bodies should guarantee compliance with the EU-wide standards of quality and safety.

These standards should include the establishment of a traceability system for human organs and a system for reporting serious adverse events or reactions.

In order to allow for an appropriate riskbenefit analysis, the collection of information on certain organ and donor characteristics should be standardised. A national quality programme should be established in the Member States to cover the entire process of organ donation and transplantation. This quality programme should ensure the constant monitoring of services, improveand learning processes. proposal provides for measures to protect the living donor: the Member States should ensure that the health of donors is correctly assessed, and that they receive all the necessary information and are entered in a register of living donors.

In addition to this, the Member States must ensure the voluntary and unpaid nature of donations of human organs from living and deceased donors.

III. Opinions of the Committees consulted

At its 124th meeting on 28 January 2009, the Legal Committee stated that the pilot phase to test compliance with the principles of subsidiarity and proportionality had been badly coordinated and that the procedure could therefore be improved. It asked the Committee on the Verification of Credentials, Immunity and the Rules of Procedure to clarify the procedure for the subsidiarity test, in principle in consultation with the other Committee Chairmen, and to draw up rules for this procedure.

At its 77th session on 28 January 2009, the EU Affairs Committee took a vote on the subsidiarity test in relation to the proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation — COM (2008)818 final; Council Doc. No 16512/08. The motion was passed with the CDU/CSU, SPD, FDP and Bündnis 90/Die Grünen voting against Die Linke. The motion was worded as followed:

"The EU Affairs Committee has examined the draft with regard to the choice of legal basis and the principle of subsidiarity. There are no concerns relating to the choice of legal basis. However, the Committee sees the need to clarify certain points in relation to compliance with the principle of subsidiarity. It is not possible to establish whether the draft Directive respects the principle proportionality as the draft does not provide detailed information on the expected financial and administrative burdens on the Member States.

Preliminary remarks

The subsidiarity check is run during a pilot phase arranged by the COSAC, during which experience must be gained of the subsidiarity control early procedure, which was established under the Lisbon Treaty and offers national parliaments a more extensive control system. As an independent subsidiarity control procedure does not currently exist under the Lisbon Treaty, the decision shall be reached under the procedure for cooperation with the Federal Government. However, this procedure is primarily intended for the European Commission. Checking compliance with the principle of examination of the proposed Directive. This is reserved for further parliamentary referral by the specialised committees and the Deutsche Bundestag in plenary session.

Justification

The basis for the vote for consultation purposes is the justification for the motion by the CDU/CSU, SPD, FDP and Bündnis 90/Die Grünen parties (A-Drs. 16(21)768), which was adopted on 28 January 2009 by majority vote at the 77th meeting of the EU Affairs Committee. The justification is as follows:

On 8 December 2008, the European Commission adopted a proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation. The draft Directive establishes the principal aim of ensuring high uniform quality and safety standards in all the process donation. of procurement, testing, preservation, transport and use – and hence a high level of health protection. The Action plan, which was published at the same time and is not legislative in nature, suggests measures intended to help increase organ availability and enhance the efficiency and accessibility of transplantation systems.

II.

The proposed Directive is based on Article 152(4) of the EC Treaty, which explicitly provides for measures setting high standards of quality and safety or organs at Community level. The objective of the Directive is to create uniform high standards of quality and safety in the Member States of the European Union.

There are no concerns with regard to the legal basis for the creation of uniform high standards of quality and safety for organs intended for transplantation across the EU. However, the Committee stresses that, in accordance with the second sentence of Article 152(5) of the EC Treaty (TEC), the donation and medical use of organs lies within the exclusive competence of the Member States and therefore does not come under the legislative competence of the Community.

In areas which do not fall within its exclusive competence, the Community shall take action, in accordance with the principle of subsidiarity, only if and in so far as the objectives of the proposed action cannot be adequately achieved by the Member States and therefore, by reason of

subsidiarity does not involve a substantive the scale or effects of the proposed action, can be better achieved by the Community. The Lisbon Treaty describes this as a competence, again prescribing compliance with the principle of subsidiarity in Article 5(3).

> The draft Directive must therefore offer proof that its objectives cannot be adequately achieved by the Member States. There are no concerns regarding the creation of uniform high standards of quality and safety across the EU for organs intended for transportation, since EU-wide uniform standards can be made binding by a European Directive. However, reference must be made in this context to the fact that the exchange of organs through Eurotransplant association is already common practice between a number of Member States and third countries.

> When checking compliance with the principle of subsidiarity, Article 18 of the draft Directive in particular must be examined prescribes closely. This more designation of competent authorities in the Member States which shall work on the basis of national quality programmes and ensure compliance with the quality and safety standards. The term "authority" in the wording of Article 18 suggests that only State bodies which perform public administration tasks are eligible. This would exclude other arrangements, such as an appointed trust, as used in Germany. Intervening in this manner in the national organisation of the health system would undermine the principle of subsidiarity.

> establishment and recognition responsible, officially recognised bodies which work on the basis of national quality programmes and ensure compliance in the respective Member States with the quality and safety standards, as provided for in Article 18 of the draft Directive, definitely serves to achieve the objectives. Indeed, it can be seen from recital 19 of the proposed Directive that the actual formation of the administrative structure is the responsibility of each individual Member State. This means that Germany would not have to create a new administrative structure.

> In order to make it clear that Article 18 of the draft Directive likewise does not undermine national sovereignty, the wording of the actual text of the Directive needs to be improved.

IV.

According to the principle of proportionality (Article 2 TEU in conjunction with Article 5(3) TEC; under the Lisbon Treaty: Article 5(4) TEU), the content and form of Community or Union action shall not exceed what is necessary to achieve the objectives of the Treaties. Consideration must be given to whether the binding effect and regulatory

density of the proposed legislation is necessary.

The shortage of organs is the key problem regards organ donations transplantation in the Member States. Institutions in the health sector such as the DKG (German Hospital Federation) and GKV (statutory health insurance) which sponsor the Deutsche Stiftung Organtransplantation and Eurotransplant, point out that no Member State has an organ surplus. However, it is questionable whether the standards of quality and safety set out in the draft Directive can actually help to remedy this shortage or foster the exchange of organs between the Member States.

The Directive sets minimum standards, i.e. the Member States can set or maintain higher quality and safety standards within their territories. At the same time, with regard to the remaining regulatory scope for the Member States, it must be borne in mind that implementing measures can be adopted by means of a committee procedure (cf. Articles 25 and 26 of the proposed Directive). It is not possible to judge from the proposed Directive alone whether such provisions can lead to an unreasonably high degree of regulation, at the expense of the Member States.

The text does not give any details as to the expected financial and administrative burdens on the Member States. It therefore cannot be established with certainty whether the provisions laid down by the Commission, such as the creation of national supervisory authorities, the authorisation of establishments and programmes for organ donation and procurement, and establishment of inspection structures might have a negative impact on the efficient organisational structure which already exists in many EU countries, and might result in considerable bureaucracy. In order to be able to judge the proportionality of the draft Directive - particularly with respect to the question of alternative solutions of a less regulatory nature, such as the conclusion of agreements between the Commission and Member States which have until now seldom engaged in the exchange of organs precise details need to be provided on potential administrative burdens. It is also the opinion of the Federal Government that the need for legislative alignment can be judged only at a later stage in the procedure."

IV. Consultation process and conclusions in the Committee with decision-making authority

In its 104th session on 21 January 2009, the Committee on Health initiated the discussion of the draft contained in BT-Drs. (Bundestag Circular) 16/11517, continuing and concluding it during its 106th meeting on 28 January 2009. In conclusion, with the CDU/CSU, SPD and Bündnis 90/Die Grünen voting against Die FDP Linke, and the abstaining, adopting the Resolution recommends presented by the CDU/CSU, SPD and Bündnis 90/Die Grünen and repeated in the recommendation for a decision. Resolution is substantiated as follows:

"Preliminary remarks

The subsidiarity check is run during a pilot phase arranged by the COSAC, during which experience must be gained of the subsidiarity control early warning procedure, which was established under the Lisbon Treaty and offers national parliaments a more extensive control system. As an independent subsidiarity control procedure does not currently exist under the Lisbon Treaty, the decision shall be reached under the procedure for cooperation with the Federal Government. However, it is intended for the European primarily Commission. It must be pointed out that checking compliance with the principle of subsidiarity shall not affect the substantive examination of the proposed Directive. This is reserved for further parliamentary referral by the specialised committees and the Deutsche Bundestag in plenary session.

Aim of the Directive

On 8 December 2008, the European Commission adopted a proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation. The Directive draft establishes the principal aim of ensuring high uniform quality and safety standards in all phases of the process donation. procurement, testing, preservation, transport and use - and hence a high level of health protection. The Action plan, which was published at the same time and is not legislative in nature, suggests measures intended to help increase organ availability and enhance the efficiency and accessibility of transplantation systems.

Legal basis

The proposed Directive is based on Article 152(4) of the EC Treaty, which explicitly provides for measures setting high standards of quality and safety for organs at Community level. The objective of the Directive is to create uniform high standards of quality and safety in the Member States of the European Union .

There are no concerns with regard to the legal basis for the creation of uniform high standards of quality and safety for organs intended for transplantation across the EU. However, the Committee stresses that, in accordance with the second sentence of Article 152(5) of the EC Treaty (TEC), the donation and medical use of organs lies within the exclusive competence of the Member States and therefore does not come under the legislative competence of the Community.

Subsidiarity

In areas which do not fall within its exclusive competence, the Community shall take action, in accordance with the principle of subsidiarity, only if and in so far as the objectives of the proposed action cannot be adequately achieved by the Member States and therefore, by reason of the scale or effects of the proposed action, can be better achieved by the Community. The Lisbon Treaty describes this as a shared competence, again prescribing compliance with the principle of subsidiarity in Article 5(3).

The draft Directive must therefore offer proof that its objectives cannot be adequately achieved by the Member States. There are no concerns regarding the creation of uniform high standards of quality and safety across the EU for organs intended for transportation, since EU-wide uniform standards can be made binding by a European Directive. However, reference must be made in this context to the fact that the exchange of organs through the Eurotransplant association is already common practice between a number of Member States and third countries.

When checking compliance with the principle of subsidiarity, Article 18 of the draft Directive in particular must be examined more closely. This prescribes the designation of competent authorities in the Member States which shall work on

the basis of national quality programmes and ensure compliance with the quality and safety standards. The term "authority" in the wording of Article 18 suggests that only bodies which perform public administration tasks as a State body are eligible. This would exclude other arrangements, such as an appointed trust, as used in Germany. Intervening in this manner in the national organisation of the health system would undermine the principle of subsidiarity.

The establishment and recognition of responsible, officially recognised bodies which work on the basis of national quality programmes and ensure compliance in the respective Member States with the quality and safety standards, as provided for in Article 18 of the draft Directive, definitely serves to achieve the objectives. Indeed, it can be seen from recital 19 of the proposed the Directive that actual formation of the administrative structure is the responsibility of each individual Member State. This means that Germany would not have to create a new administrative structure.

In order make it clear that Article 18 of the draft Directive likewise does not undermine national sovereignty, the wording of the actual text of the Directive needs to be improved.

Proportionality

According to the principle of proportionality (Article 2 TEU in conjunction with Article 5(3) TEC; under the Lisbon Treaty: Article 5(4) TEU), the content and form of Community or Union action shall not exceed what is necessary to achieve the objectives of the Treaties. Consideration must be given to whether the binding effect and regulatory density of the proposed legislation is necessary.

The shortage of organs is the key problem as regards organ donations and transplantation in the Member States. Institutions in the health sector such as the DKG and GKV, which sponsor the Deutsche Stiftung Organtransplantation and Eurotransplant, point out that no Member State has an organ surplus.

The Directive sets minimum standards, i.e. the Member States can set or maintain higher quality and safety standards within their territories. At the same time, with regard to the remaining regulatory scope for the Member States, it must be borne in mind that implementing measures can be adopted by means of a committee procedure (cf. Articles 25 and 26 of the proposed Directive). It is not possible to judge from the proposed Directive alone whether such provisions can lead to an unreasonably high degree of regulation, at the expense of the Member States.

The text does not give any details as to the expected financial and administrative burdens on the Member States. It therefore

cannot be established with certainty whether the provisions laid down by the Commission, such as the creation of national supervisory authorities, establishments authorisation of and programmes for organ donation and procurement, and the establishment of inspection structures might have a negative impact on the efficient organisational structure which already exists in many EU countries, and might result in considerable bureaucracy. In order to be able to judge the proportionality of the draft Directive particularly with respect to the question of alternative solutions of a less regulatory such as the conclusion agreements between the Commission and Member States which have until now seldom engaged in the exchange of organs precise details need to be provided on potential administrative burdens. It is also the opinion of the Federal Government that the need for legislative alignment can be judged only at a later stage in the procedure.'

A motion for a Resolution from the *Die Linke* party was also submitted to the Committee. The Committee rejected the motion, set out below, with the CDU/CSU, SPD, FDP and *Bündnis 90/Die Grünen* voting against the *Die Linke* party:

"The Deutsche Bundestag:

on the basis of the briefing – Circular 16/11517 No A 30 – is called on to adopt the following Resolution

The Deutsche Bundestag declares:

The Deutsche Bundestag has examined the proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation with respect to the choice of legal basis and the principles of subsidiarity and proportionality.

The Deutsche Bundestag expresses concern with regard to the choice of legal basis for some of the proposed provisions.

The Deutsche Bundestag declares that there is cause for concern regarding compliance with the principle of subsidiarity.

It is not possible to determine whether the draft Directive respects the principle of proportionality.

Furthermore, the proposal for a Directive on standards of quality and safety of human organs intended for transplantation must be examined at a later date.

Justification:

Preliminary remarks

The subsidiarity check is run during a pilot phase arranged by the COSAC, during which experience must be gained of a subsidiarity control early warning procedure, which may need to be

established. As an independent subsidiarity control procedure does not currently exist, the decision shall be reached under the procedure for cooperation with the Federal Government. However, it is primarily intended for the European Commission. It must be pointed out that checking compliance with the principle of subsidiarity shall not affect the substantive examination of the proposed Directive. This is reserved for further parliamentary referral by the specialised committees and the Deutsche Bundestag in plenary session.

Aim of the Directive

On 8 December, the European Commission adopted a proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for The transplantation. draft Directive establishes the principal aim of ensuring high uniform quality and safety standards in all phases of the process - donation, procurement, testing, preservation, transport and use – and hence a high level of health protection. The Action plan, which was published at the same time and is not legislative in nature, suggests measures intended to increase organ availability and enhance the efficiency and accessibility of transplantation systems.

Legal basis

The proposed Directive is based on Article 152(4) of the EC Treaty, which explicitly provides for measures setting high standards of quality and safety for organs at Community level. The objective of the Directive is to create uniform high standards of quality and safety in the Member States of the European Union.

Only as regards the establishment of a high uniform EU minimum standard for quality and safety requirements for organs intended for transplantation are there no concerns relating to the legal basis.

In accordance with the second sentence of Article 152(2) TEC, the donation and medical use of human organs is completely beyond the Community field of competence. The proposed Directive oversteps this clear competence framework on several points, thereby unduly encroaching on the genuine responsibility of the Member States. The same applies for the provisions set out in Articles 4(2)(b), 13, 14, 15(1) and 17. An EU Directive on the quality and safety of human organs may cover only the use of test procedures to detect infectious and tumoral diseases (risk assessment), the preservation, transportation and guaranteed traceability of organs, and the reporting of any serious adverse events after transplantation.

Nor do the proposed provisions on the creation and designation of responsible authorities, procurement organisations. transplantation centres and organ exchange organisations in Articles 18 ff. come under

the competence standard set out in Article 152 TEC.

Lastly, Article 152 TEU does not provide a sufficient legal basis for the creation of a new institution appointed as a Committee (Article 26) whose tasks, composition and formation are not specified.

Subsidiarity

In areas which do not fall within its exclusive competence, the Community shall take action, in accordance with the principle of subsidiarity, only if and in so far as the objectives of the proposed action cannot be adequately achieved by the Member States and therefore, by reason of the scale or effects of the proposed action, can be better achieved by the Community.

The proposed Directive gives rise to no concerns in relation to the creation of EU-wide uniform standards of quality and safety for organs intended for transplantation.

However, these uniform material standards can be implemented and controlled in the same manner and as required in the Member States using different procedures the context of different in organisational systems and institutions. Efficient transplantation systems already exist in Germany, and in other Member States, although this is not the case in all EU Member States. Consequently, there is a risk of higher standards being lowered. The extent to which the goals of the Directive can be furthered through the creation of new national supervisory authorities. the authorisation establishments and the approval of organ procurement and transplantation programmes, as provided for in the proposed Directive, is unclear.

This applies in particular with regard to the complex provisions of Article 18 of the draft Directive. The term "authority" in the wording of Article 18 suggests that only bodies which perform public administration tasks are eligible. This would exclude other arrangements, such as an appointed trust, as used in Germany. Intervening in this manner in the national organisation of the health system would undermine the principle of subsidiarity. Even if the wording of the Directive or of one of its recitals allowed the current specific form of administrative structure in Germany to be maintained, this would be beside the point. The problem is that the Directive undermines the regulatory authority of the Member States, preventing them from shaping or reshaping their structures independently, without improvement in the achievement of the set objectives.

Proportionality

According to the principle of proportionality (Article 2 TEU in conjunction with Article

5(3) TEC), the content and form of Community or Union action shall not exceed what is necessary to achieve the objectives of the Treaties. Consideration must be given to whether the binding effect and regulatory density of the proposed legislation is necessary and whether the financial and organisational burdens on the Member States are not unreasonable.

The text does not give any details as to the expected financial and administrative burdens on the Member States. It therefore cannot be established with certainty whether the provisions laid down by the Commission, such as the creation of national supervisory authorities, the authorisation of establishments and programmes for organ donation procurement, and and establishment of inspection structures might have a negative impact on the efficient organisational structure which already exists in many EU countries, and might result in considerable bureaucracy. Exact details on the administrative burdens would be needed to rule out the possibility of the draft Directive being disproportionate. Until the Commission presents a draft Directive which includes these details, the draft must be rejected on account of a breach of the principle of proportionality."

In principle, the CDU/CSU, SPD and Bündnis 90/Die Grünen were of the opinion that, owing to its complexity, the proposed Directive was only partly suited to the subsidiarity test. They also stressed the of differentiating between importance questions relating to the content of the proposed Directive and those relating to subsidiarity. The only current issue is that of subsidiarity and the parties which adopted the motion contained in A-Drs. 478 have no concerns over the chosen legal basis. Nevertheless, they consider that a number of points need to be clarified, in particular Article 18 of the proposed Directive and the term "competent authority" used therein. It is questionable whether this model can be reconciled with the practice in Germany of appointing a trust to coordinate organ donations. Although recital 19 of the proposal indicates that this may be the case, needs to be stated clearly unequivocally in the Directive itself. Furthermore, there is a lack of clarity regarding compliance with the principle of proportionality, in so far as the administrative structure provided for by the European Commission, among other things, could give rise to considerable additional administrative and financial burdens on the Member States.

The motion by the *Die Linke* party contained in A-Drs. 479 does not take sufficient account of the fact that the European Commission has not prescribed a specific administrative structure. Instead, in recital 19 of the draft, the Commission refers specifically to the respective repartition of competences in the Member States. The CDU/CSU, SPD and

Bündnis 90/Die Grünen therefore reject this motion.

The FDP was of the opinion that that further clarification was necessary regarding compliance with the principle of subsidiarity. In principle, the FDP could in principle have supported the motion by the coalition and Bündnis 90/Die Grünen, but it considered that the motion should also include a complete check of Chapter III of the proposed Directive for compatibility with the principle of subsidiarity. However, the coalition is against this proposal and the FDP therefore abstains from voting on the motion contained in A-Drs. 478.

The FDP rejects the motion by *Die Linke* contained in A-Drs. 479 because it has a different focus as regards the legal basis.

Die Linke is surprised that the majority of Committee members do not wish to express concern regarding compliance with the principle of subsidiarity. This party has therefore submitted its own motion for a Resolution. In its opinion, the proposed Directive does give cause for concern, firstly on account of its choice of legal basis for some of the proposed provisions, and secondly owing to the principle of

subsidiarity being violated, since detailed institutional provisions are not necessary to ensure compliance with quality standards. Furthermore, it is impossible to determine whether the draft Directive respects the principle of proportionality, as the Commission has not provided the necessary relevant information. The proposal for a Directive should remain subject to examination at a later date.

In conclusion, *Die Linke* stresses that it is not against but in favour of a social Europe and wishes to pursue the process of European integration. However, it is important to prevent higher standards from being undermined. Basically, clarification on the respective fields of competence of the European Union and the Member States is required.

Die Linke considers that the approach advocated by the coalition and the Bündnis 90/Die Grünen party of asking the Commission to provide clarification is not enough to effectively counter the risks of the proposed Directive. It therefore rejects the motion by the coalition and the Bündnis 90/Die Grünen party contained in A-Drs. 478.

Berlin, 28 January 2009

Committee on Health

Michael Hennrich, CDU/CSU