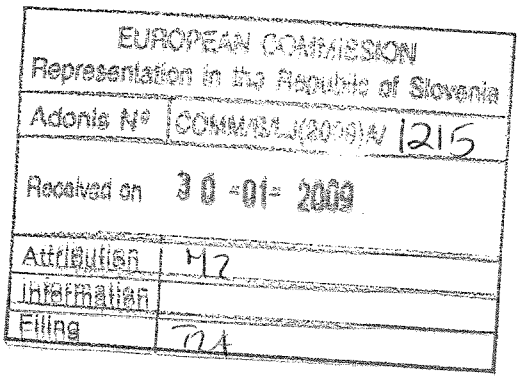
REPUBLIKA SLOVENIJA
DRŽAVNI ZBOR

Odbor za zadeve Evropske unije



Gospa mag.
Mihela Zupančič,
Vodja Predstavništva
Predstavništvo Evropske komisije v Sloveniji
Breg 14
1000 Ljubljana

Št. 008-19/08-8/4
Datum: 29. 1. 2008

Spoštovani,

V prilogi Vam pošiljamo rezultate testa o nadzoru načela subsidiarnosti o *Predlogu Direktive Evropskega parlamenta in Sveta o standardih kakovosti in varnosti človeških organov, namenjenih za presaditev*, ki smo ga izvedli kot enega od pilotskih projektov v okviru COSAC-a, tj. Konference odborov parlamentov Evropske unije za evropske zadeve, na osnovi določb Lizbonske pogodbe.

Prosimo Vas, da jih posredujete podpredsednici Komisije in komisarki za institucionalne odnose in komunikacijsko strategijo dr. Margot Wallström ter pristojnemu generalnemu direktoratu.

Lep pozdrav,

REPUBLIKA SLOVENIJA DRŽAVNI ZBOR 6 LJUBLJANA

Darja Lavtižar Bebler
predsednica

Prilogi: 2

Šubičeva 4, 1000 Ljubljana, Slovenija
telefon: 01 478 98 22, 01 478 95 05, faks: 01 478 98 58

REPUBLIKA SLOVENIJA
DRŽAVNI ZBOR

Odbor za zadeve Evropske unije

Številka: 008-19/08-8/6
Datum: 23. 1. 2009

Odbor za zadeve Evropske unije

Odbor za zadeve Evropske unije je na 7. seji 23. 1. 2009 ob obravnavi 6. točke z naslovom "Obrazloženo mnenje o upoštevanju načela subsidiarnosti pri Predlogu direktive Evropskega parlamenta in Sveta o standardih kakovosti in varnosti človeških organov, namenjenih za presaditev" sprejel naslednji

SKLEP:

Odbor za zadeve Evropske unije ob upoštevanju mnenja Odbora za zdravstvo z dne 21. 1. 2009 ter mnenja Zakonodajno-pravne službe z dne 15. 1. 2009 ugotavlja, da *Predlog direktive Evropskega parlamenta in Sveta o standardih kakovosti in varnosti človeških organov, namenjenih za presaditev* upošteva načelo subsidiarnosti v skladu s postopkom iz *Protokola o uporabi načel subsidiarnosti in sorazmernosti*, ki je priložen *Pogodbi o Evropski uniji in Pogodbi o delovanju Evropske unije.*

REPUBLIKA SLOVENIJA DRŽAVNI ZBOR 6 LJUBLJANA

D. Lavtižar Bebler

Darja Lavtižar Bebler
predsednica

V vednost:
- Kolegiju predsednika Državnega zbora
- Odboru za zdravstvo

Šubičeva 4, 1000 Ljubljana, Slovenija
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REPUBLIKA SLOVENIJA
DRŽAVNI ZBOR

Odbor za zdravstvo

Številka: 008-19/08-8/5
Ljubljana: 21.1.2009

ODBORU ZA ZADEVE EVROPSKE UNIJE

Ob smiselni uporabi drugega odstavka 154.h člena Poslovnika Državnega zbora Republike Slovenije (Ur.list RS., štev.: 35/2002, 60/2004, 64/2007) daje Odbor za zdravstvo kot **matično delovno telo** naslednje

M N E N J E

O upoštevanju načela subsidiarnosti v skladu s postopkom iz Protokola o uporabi načel subsidiarnosti in sorazmernosti, ki je priložen pogodbi o Evropski uniji in Pogodbi o delovanju Evropske unije, glede Predloga direktive Evropskega parlamenta in Sveta o standardih kakovosti in varnosti človeških organov namenjenih za presaditev

Odbor Državnega zbora Republike Slovenije za zadeve Evropske unije je na svoji 4. seji dne 12.12.2008 ob obravnavi 7. točke dnevnega reda sprejel sklep, na podlagi katerega je pozval Odbor Državnega zbora Republike Slovenije za zdravstvo, da mu posreduje obrazloženo mnenje o tem ali Predlog Direktive Evropskega parlamenta in Sveta o standardih kakovosti in varnosti človeških organov, namenjenih za presaditev upošteva načelo subsidiarnosti v skladu z postopkom iz Protokola o uporabi načel subsidiarnosti in sorazmernosti, ki je priložen Pogodbi o Evropski uniji in Pogodbi o delovanju Evropske unije.

Odbor Državnega zbora Republike Slovenije za zdravstvo je test subsidiarnosti glede predlaganega sklepa izvedel na svoji 1. redni seji dne 21.1.2009.

G. Matevž Frangež, podpredsednik Odbora za zadeve Evropske unije, je kot pobudnik zadeve uvodoma pojasnil, da je v okviru COSAC-a, takoimenovane Konference odborov parlamentov Evropske unije za evropske zadeve, vsako leto sprejeta odločitev, da se v vseh nacionalnih parlamentih držav članic letno izvede vsaj dva testa o nadzoru načela subsidiarnosti glede skupno izbranih predlogov zakonodajnih aktov. Tako je bil lanskega julija na srečanju predsednikov odborov v Parizu sprejet sklep o izvedbi testa subsidiarnosti o Predlogu direktive Evropskega parlamenta in Sveta o standardih kakovosti in varnosti človeških organov, namenjenih za presaditev. Predlog tega akta je bil v vseh uradnih jezikih Unije objavljen 10. 12. 2008, ko je začel teči 8-tedenski rok za izvedbo testa subsidiarnosti. Ta rok je predviden v omenjenem Protokolu o uporabi načel subsidiarnosti in sorazmernosti Lizbonske pogodbe. Pri izvedbi testa

subsidiarnosti za enega tako imenovanih pilotskih projektov, naj bi se pokazalo, kakšno bo konkretno delovanje in sodelovanje parlamentov na tem področju, predvsem ko bo Lizbonska pogodba stopila v veljavo.

Glede na to, da je smisel izvedbe teh testov čim večja vključenost nacionalnih parlamentov v tako imenovani predhodni postopek, je bil v skladu z uveljavljeno prakso na 4. seji Odbora za zadeve EU 12. 12. 2008 sprejet sklep, da se predlog direktive in delovni dokument, ki ga je pripravil sekretariat COSAC-a, posredujeta matičnemu delovnemu telesu - Odboru za zdravstvo ter Zakonodajno-pravni službi, da pripravita obrazloženo mnenje o tem ali predlog upošteva načelo subsidiarnosti, tako kot je določeno v omenjenem protokolu. Po seznanitvi z mnenjem na Odboru za zadeve EU bo strokovna služba odbora pripravila ustrezno poročilo, ki bo posredovano sekretariatu COSAC-a. Na osnovi vseh prejetih poročil s strani nacionalnih parlamentov držav članic bo na zasedanju COSAC-a maja 2009 o morebitni ugotovljeni kršitvi načela subsidiarnosti pri tem predlogu akta ter o uspešnosti izvedbe samega testa opravljena ustrezna razprava.

V Lizbonski pogodbi je v novem institucionalnem ustroju večji pomen dan nacionalnim parlamentom držav članic. V zadnjih nekaj letih se je namreč kompleksno vprašanje njihove vključenosti v postopke odločanja na evropski ravni ponovno postavljalo v ospredje, in to predvsem iz dveh razlogov. Po eni strani je to povezano z naraščanjem števila zakonodajnih aktov, sprejetih na ravni Skupnosti oz. Unije, ki jih je treba prenesti v nacionalno zakonodajo, po drugi strani pa s stalnim poudarjanjem tako imenovanega demokratičnega primanjkljaja na strani institucij Evropske unije.

Novi 12. člen Pogodbe o Evropski uniji poudarja, da k dobremu delovanju Unije dejavno prispevajo tudi nacionalni parlamenti. Pri tem je izpostavljena njihova vloga, predvsem v skrbi za spoštovanje načela subsidiarnosti, kot je določeno v Protokolu o uporabi načel subsidiarnosti in sorazmernosti. V skladu z načelom subsidiarnosti Evropska unija "deluje na področjih, ki niso v njeni izključni pristojnosti le, če in kolikor države članice ciljev predlaganih ukrepov ne morejo zadovoljivo doseči na nacionalni, regionalni ali lokalni ravni, temveč se zaradi obsega in učinkov predlaganih ukrepov lažje dosežejo na ravni Unije". Pri nadzoru spoštovanja tega načela gre za to, da se prepreči, da bi Unija pri delovanju posegala na področja, ki niso v njeni pristojnosti, ampak le-te ostajajo v pristojnosti držav članic.

Mag.Samo Kutoš predstavnik Zakonodajno pravne službe je povzel svoje pisno mnenje v katerem je uvodoma najprej podal splošno definicijo načela subsidiarnosti in sorazmernosti, nadalje javno zdravje in subsidiarnost ter subsidiarnost v navedenem predlogu Direktive Evropskega parlamenta in Sveta. Kljub nekaterim izraženim pomislekom predvsem formalne narave, Zakonodajno pravna služba presoja, da predlog upošteva načelo subsidiarnosti.

K Predlogu direktive Evropskega parlamenta in Sveta je svoje mnenje posredoval tudi Državni Svet Republike Slovenije in sicer Komisija za socialno varstvo, delo, zdravstvo in invalide in Komisija za mednarodne odnose in evropske zadeve. Mnenje je na seji odbora predstavil državni svetnik Peter Požun in poudaril, da Komisiji ugotavljata, da so

standardi kakovosti in varnosti človeških organov namenjenih presajanju v Sloveniji, na podlagi določb Zakona o odvzemu in presaditvi delov človeškega telesa zaradi zdravljenja (Ur.list RS, št.:12/00,61/07) ter z njim povezanih podzakonskih aktov na visokem nivoju. Zakon je kot pristojno neprofitno institucijo na nivoju države določil Zavod RS za presaditev organov in tkiv - Slovenija Transplant.

Komisiji nadaljne ugotavljata,da na tem področju Slovenija spada med naprednejše evropske države in aktivno sodeluje pri razvoju tega področja na nivoju EU, saj se Slovenija z 20 darovalci na milijon prebivalcev na leto uvršča nad evropsko povprečje. Izpostavljen je bil 11 člen direktive, ki ureja sisteme za poročanje o hudih neželenih dogodkih in reakcijah, ker je premalo definiran v smislu osnovnega poenotenja postopkov v takšnih primerih ter zato ne bo zagotavljal enakega nivoja varnosti v vseh državcah članicah EU. Slovenija ima to področje dobro urejeno, saj so se že leta 2000 na podlagi zakona uveljavili posebni protokoli glede zasledovanja poti organa namenjenega za presaditev. Pooblastilo izvajanja nadzora je bilo dano Slovenija Transplant-u, ki to nalogo izvršuje skrbno in vestno. Komisiji Državnega sveta RS sta ugotovili, da Predlog direktive Evropskega parlamenta in Sveta o standardih kakovosti in varnosti človeških organov ni v neskladju z načelom subsidiarnosti, sta pa pozvali Vlado RS in Ministrstvo za zdravje, da se pri nadaljnih postopkih vezanih na predlog direktive zavzemata za ponovno proučitev člena 11 v zvezi z strožjim zagotavljanjem delovanja sistemov za poročanje o hudih neželenih dogodkih in reakcijah.

Predstavnik Ministrstva za zdravje - direktor direktorata g. Janez Remškar je poudaril, da je predlog stališča Republike Slovenije do predloga direktive v pripravi in bo skladno z zakonom o sodelovanju med državnim zborom in vlado v zadevah Evropske unije posredovan v državni zbor. Glede na to, da se zakonodaja glede kakovosti in varnosti človeških organov namenjenih za presaditev med posameznimi državami članicam razlikuje, je smiselno to področje urediti na ravni EU. Ministrstvo za zdravje zato ocenjuje, da predlog direktive upošteva načelo subsidiarnosti.

V razpravi so člani odbora poudarili, da glede na vsa predstavljena mnenja izhaja, da predlog direktive vsebuje vsa navedena načela, Posebej je bilo poudarjeno, da je navedena tematika strokovno zelo občutljiva in da ima Slovenija na tem področju zavidljive rezultate ter urejeno zakonodajo.

Odbor je po zaključeni razpravi sprejel naslednje

M n e n j e:

Odbor Državnega zbora Republike Slovenije za zdravstvo meni, da Predlog direktive Evropskega parlamenta in Sveta o standardih kakovosti in varnosti človeških organov, namenjenih za presaditev upošteva načelo subsidiarnosti v skladu s postopkom iz Protokola o uporabi načel subsidiarnosti in sorazmernosti, ki je priložen Pogodbi o Evropski uniji in Pogodbi o delovanju Evropske unije.

Poročevalec na seji pristojnega delovnega telesa bo član odbora g. Anton Colarič.

Mag. Hedvika Stanič Igličar
Sekretarka odbora

Ljubo Germič
Predsednik

Poslano:
- Vladi Republike Slovenije
- Državnemu svetu Republike Slovenije
- Ministrstvu za zdravje
- Zakonodajno pravni službi
- Vodjem poslanskih skupin

REPUBLIKA SLOVENIJA
DRŽAVNI ZBOR
* * *

Zakonodajno - pravna služba

Številka: 008-19/08-8/3
Datum: 15. 1. 2009

ODBOR ZA ZADEVE EVROPSKE UNIJE

Zadeva: Mnenje o upoštevanju načela subsidiarnosti pri predlogu Direktive Evropskega parlamenta in Sveta o standardih kakovosti in varnosti človeških organov, namenjenih za presaditev

Odbor za zadeve Evropske unije je dne 12. decembra 2008 pozval ZPS, da pripravi obrazloženo mnenje, ali predlog direktive, navedene v naslovu (v nadaljevanju: predlog) upošteva načelo subsidiarnosti po Protokolu o uporabi načel subsidiarnosti in sorazmernosti (v nadaljevanju: Protokol), ki je priložen Pogodbi o Evropski uniji (PEU) in Pogodbi o ustanovitvi Evropske skupnosti (PES).

Splošno o načelu subsidiarnosti in sorazmernosti
Načelo subsidiarnosti in sorazmernosti je določeno v členu 5(2) PES: po tem načelu Unija deluje (npr. sprejema pravne akte) na področjih, ki niso v njeni izključni pristojnosti, le če in kolikor države članice ciljev predlaganih ukrepov ne morejo zadovoljivo doseči na nacionalni, regionalni ali lokalni ravni (negativno merilo oz. test nujnosti), temveč se zaradi obsega ali učinkov predlaganih ukrepov lažje dosežejo na ravni Unije (pozitivno merilo oz. test dodane vrednosti). Pozitivno in negativno merilo morata biti izpolnjena kumulativno. Načelo sorazmernosti je opredeljeno v tretjem odstavku istega člena: ukrepi Unije ne smejo presegati tistega, kar je potrebno za doseganje ciljev ustanovitvenih pogodb. Način uporabe (izvrševanja) tega načela določa Protokol v 5. členu: vsak osnutek zakonodajnega akta mora vsebovati podrobno izjavo, ki omogoča oceno skladnosti osnutka z načelom subsidiarnosti. Posebej je določeno, da mora podrobna izjava vsebovati podatke o finančnih učinkih. V primeru direktive mora izjava vsebovati tudi podatke o predvidenih posledicah za pravila, ki jih morajo sprejeti države članice. Razlogi za zaključek, da se lahko cilj Unije laže uresniči na ravni Unije, se morajo utemeljiti s kvalitativnimi in, če je možno, kvantitativnimi kazalci. Navsezadnje

člen 5 Protokola zahteva, da morajo osnutki upoštevati potrebo, da so finančni ali upravni stroški čim nižji in sorazmerni s ciljem, ki ga želijo doseči.
Poleg splošne ureditve načela subsidiarnosti v členu 5 PES je pri nekaterih posameznih področjih načelo konkretizirano v določbah Pogodbe o zadevnem področju. Tako je tudi pri področju javnega zdravja, urejenem v Naslovu XIII PES.

Javno zdravje in subsidiarnost
Edini člen Naslova XIII je člen 152. V prvem odstavku določa, da se mora zagotavljati visoka raven varovanja zdravja ljudi pri opredeljevanju in izvajanju vseh politik in dejavnosti Skupnosti (t. i. *mainstreaming*). V drugem in tretjem pododstavku istega odstavka sta posebej izpostavljeni področji obvladovanja močno razširjenih težkih bolezni in boja proti uživanju drog. V drugem pododstavku drugega odstavka je prvič opredeljeno načelo subsidiarnosti, saj določa, da (primarno) države članice v sodelovanju s Komisijo usklajujejo svoje politike in programe na navedenih področjih. Tretji odstavek določa mednarodno sodelovanje.
Za obravnavani predlog je relevanten predvsem četrti odstavek, ki v točki (a) določa, da se v postopku t. i. soodločanja (*codecision*) po členu 251 PES sprejema, med drugim, (zakonodajne) ukrepe, ki določajo visoke standarde kakovosti in varnosti organov in snovi človeškega izvora ter krvi in krvnih derivatov. Tudi točka (a) vsebuje omejitev v smislu načela subsidiarnosti, saj določa, da sprejeti zakonodajni ukrepi državam članicam ne preprečujejo ohranjanja ali uvedbe strožjih zaščitnih ukrepov. Dodatna omejitev v smislu načela subsidiarnosti je v petem odstavku člena 152, ki najprej poudari, da je pri dejavnosti Skupnosti na tem področju v celoti upoštevana odgovornost (smiselno: pristojnost) držav članic za organizacijo in zagotavljanje zdravstvenih storitev in varstva. Konkretna omejitev pristojnosti Skupnosti je, da ukrepi na podlagi odstavka (4)(a) ne vplivajo na nacionalne določbe o darovanju organov in krvi ali njihovi uporabi za namene zdravljenja. Določbi odstavkov 4(1) in (5) je potrebno brati skupaj tako, da bosta smiselna. Ni namreč možna razlaga, da bi odstavek (5) področje darovanja organov v celoti izključil iz zakonodajnega urejanja EU, saj bi to dobesedno pomenilo, da standardi kakovosti po odstavku (4)(a) ne bi veljali za organe, ki se darujejo. Zato je treba določbi brati tako, da standardi kakovosti, ki jih sprejema EU, seveda veljajo tudi za organe, ki se darujejo. Ostala vprašanja v zvezi z darovanjem organov, ki ne zadevajo standardov, pa ostajajo v pristojnosti držav članic. V praksi gre tu npr. za vprašanje dopustnosti darovanja med sorodniki, vprašanje oblike soglasja (gl. spodaj) itd.
Na podlagi člena 152(4)(a) sta že bili sprejeti Direktiva 2002/98 o krvi in krvnih derivatih ter Direktiva 2004/23 o človeških tkivih in celicah, sprejeti pa so bili tudi nekateri izvedbeni akti za navedeni direktivi. Obravnavani predlog zajema tretje področje člena 152(4)(a).

Subsidiarnost v predlogu
Elementi izjave o subsidiarnosti in sorazmernosti so v uvodni obrazložitvi predloga. Podatki o predvidenih finančnih učinkih osnutka in upoštevanja zahteve po čim nižjih stroških so izčrpno navedeni v "Zakonodajnem finančnem izkazu"; za ta izkaz ZPS

presoja, da je ustrezen. Posebej izpostavljamo, da so finančni učinki seveda navedeni številčno, s čimer se izpolnjuje tudi zahteva po kvantitativni oceni.
Osrednji del presoje skladnosti z načelom subsidiarnosti je presoja negativnega in pozitivnega merila. Gre za t.i. test primerjalne učinkovitosti, torej ali se lahko cilj Unije laže uresniči na ravni Unije kot pa na ravni držav članic. Izpolnjevanje kriterijev je vsebovano v razdelku "Dodana vrednost Direktive", ki presoja predvsem izpolnjevanje t.i. pozitivnega merila. Posebej relevanten je zadnji odsek navedenega razdelka o "Pospeševanju sodelovanja med državami članicami in čezmejnih izmenjavah": v 27. točki je naveden cilj zagotavljanja visoke stopnje kakovosti in varnosti celotnega postopka presajanja organov v *vseh* državah članicah ob upoštevanju prostega pretoka državljanov in potrebi po povečanju čezmejne izmenjave organov. Zaradi tega morajo biti evropski državljani prepričani, da po vseh državah članicah veljajo enaki standardi kakor v njihovi lastni državi. Potrebnost čezmejne izmenjave je utemeljena v 28. točki predvsem z dejstvom, da je za izpolnjevanje potreb vseh bolnikov na čakalnih seznamih potreben velik krog darovalcev, zlasti pri posebej občutljivih pacientih. V točkah 29-31 so izčrpno obrazloženi mehanizmi, s katerimi predlog dosega te cilje. Posebej izpostavljamo tudi 24. točko obrazložitve, ki v skladu s subsidiarnostjo izrecno navaja, da predlog direktive ne obravnava nekaterih občutljivih etičnih vprašanj glede ureditve soglasja k darovanju organov.
Uvodna obrazložitev po presoji ZPS načeloma ustreza zahtevam po obrazložitvi predloga glede skladnosti s subsidiarnostjo. Prav tako je v skladu s subsidiarnostjo tudi vsebina določb predloga, ki se nanašajo na transnacionalne elemente presajanja organov znotraj celotne EU v skladu z doseganjem ciljev predloga. Poglavju II predloga ureja organizacije in postopke (pridobivanja, sledljivosti, prevoza, poročanja itd.), ki naj zagotovijo standarde kakovosti in varnosti, kakor so podrobneje razloženi v poglavju III predloga. Poglavje IV ureja način izmenjave informacij med državami članicami, Poglavje V pa s tretjimi državami. Poglavje VI (Splošne določbe) vsebuje enake določbe kot večina direktiv. Predlog torej v svojih določbah vsebuje predvsem določbe, ki so očitno namenjene vzpostavljanju enakih standardov kakovosti in varnosti v vseh državah članic, kar ustreza vsebini člena 152(4)(a).
ZPS presoja, da je vprašanje ureditve darovanja organov v predlogu potrebno podrobnejšega premisleka. Kot je že navedeno zgoraj, člen 152(5) izrecno prepoveduje, da bi zakonodajni ukrepi EU vplivali na nacionalno ureditev o darovanju organov. V zvezi s tem je nujno opozoriti na člena 13 in 14 predloga, ki na prvi pogled v nasprotju z navedeno določbo urejajo darovanje organov. Člen 13 že po naslovu vsebuje načela, ki urejajo darovanje organov, in sicer da morajo države članice darovanje organov tako živih kot mrtvih darovalcev normativno urediti kot prostovoljno in brezplačno (prvi odstavek), da je oglaševanje darovanja organov za pridobitne namene prepovedano (drugi odstavek) in da se pridobivanje organov izvaja na nepridobitni podlagi (tretji odstavek). Po členu 14 se pridobivanje lahko izvaja šele, ko so izpolnjene zahteve glede soglasja in odobritve, ki veljajo v zadevni državi članici. Ta druga določba je zapisana tako, da ne pomeni poseganja v pristojnost države članice, saj pridobivanje izrecno veže na *nacionalne* zahteve in pogoje, ne pa na pogoje, ki bi jih postavljala sama direktiva. Zato člen 14 sploh ne posega v pristojnosti držav članic.
Še vedno ostaja odprto vprašanje, ali je obvezna določitev brezplačnega in nepridobitnega darovanja organov v členu 13 poseg v prepoved urejanja darovanja po odstavku (5), kakor je bila razložena zgoraj. Vprašanje se zastavlja zlasti ob primerjavi s

sorodno določbo Direktive 2004/23 o krvi in krvnih derivatih, ki v členu 12(1) določa, da si države članice zgolj "prizadevajo" zagotoviti brezplačno darovanje krvi. V drugem pododstavku istega odstavka člena 12 Direktiva 2004/23 celo določa možnost nadomestila v nekateri primerih. Člen 13 predloga pa nasprotno države članice *zavezuje* k brezplačnosti.

Kot odgovor na ta morebitni pomislek ZPS najprej opozarja, da že pomen besede "darovanje" izključuje možnost pridobitnega namena, saj bi tedaj šlo za "trgovanje". Dodatno pa opozarja na ustaljeno temeljno načelo prava EU, da je Unija zavezana spoštovati človekove pravice, kakor izhajajo iz ustavnih tradicij držav članic, kakor tudi iz mednarodnih sporazumov o človekovih pravicah. To načelo Sodišče ES oz. EU ustaljeno potrjuje od zadeve *Nold proti Komisiji* (1974 ECR 491) dalje. Opozarjamo tudi na člen 6 PEU, ki v prvem odstavku ponavlja načelo iz odločitve *Nold*, v drugem odstavku pa se izrecno sklicuje na Evropsko konvencijo o človekovih pravicah (EKČP). Vse države članice EU so tudi podpisnice EKČP, ki je torej del njihovega "notranjega" pravnega reda. V zvezi z obravnavanim predlogom je zato posebej pomemben 16. uvodni odstavek predloga, ki navaja Konvencijo Sveta Evrope o človekovih pravicah in biomedicini. Ta konvencija je akt, ki temelji na EKČP in zanj zato prav tako velja člen 6(2) PEU. Navedena Konvencija po navedbi v 16. uvodnem odstavku izrecno zahteva prostovoljno in brezplačno darovanje. Natančneje je to vprašanje urejeno v 21. členu Dodatnega protokola o presaditvi človeških organov in tkiv h Konvenciji o človekovih pravicah v zvezi z biomedicino, ki v prvem odstavku določa prepoved pridobivanja premoženjske koristi v zvezi s človeškim telesom in njegovimi deli, torej tudi organi (v drugem pododstavku je resda dopuščena možnost nadomestil, a tu gre za povračilo izgubljenega zaslužka in stroškov, ne pa za plačilo za darovanje organa). V drugem odstavku 21. člena Dodatnega protokola je prepovedano oglaševanje s pridobitnim namenom. Določba člena 13 predloga torej smiselno ustreza določbi 21. člena Dodatnega protokola. Ker je ta na podlagi člena 6(2) PEU in zaradi judikature Sodišča EU del pravnega reda EU in držav članic glede varstva človekovih pravic, zato prepoved po členu 13 predloga le ponavlja normo, ki je že del pravnega reda držav članic in zato ne posega v njihovo pristojnost v nasprotju z načelom subsidiarnosti.

Prav tako pomembno je tudi sklicevanje na Listino o temeljnih pravicah EU v 16. uvodnem odstavku predloga: Listina v tretji alineji drugega odstavka člena 3 podobno kot Dodatni protokol prepoveduje uporabo človeškega telesa in njegovih delov zaradi premoženjske koristi. Zaradi neuspešne ratifikacije Pogodbe o Ustavi za Evropo in še nedokončane ratifikacije Lizbonske pogodbe Listina sicer ni pravno zavezujoč akt. Sodišče EU pa je v zadevi C-540/03 (*Evropski parlament proti Svetu* [2006] ECR I-5769) vendarle poudarilo, da Listina potrjuje človekove pravice, kakor izhajajo iz ustavnih tradicij držav članic, mednarodnih sporazumov in pravnih aktov primarne in sekundarne zakonodaje EU, s čimer ji je podelilo razlagalno moč pri ugotavljanju, katere norme glede človekovih pravic tvorijo del pravnega reda EU. Ker je nepridobitnost uporabe človekovega telesa in njegovih delov, torej tudi organov, navedena v Listini, je načelo nepridobitnosti tudi sestavni del prava EU, ki ga morajo države članice upoštevati.

ZPS torej presoja, da z vsebinskega stališča člen 13 ni v nasprotju z načelom subsidiarnosti. Ob tem sicer dodaja, da bi lahko predlog za ustreznejšo zadovoljitev formalnih (proceduralnih) zahtev vseboval podrobnejšo in eksplicitno obrazložitev glede obravnavanih vprašanj. 23. uvodni odstavek predloga vsebuje splošen sklic na načelo subsidiarnosti, kakor je določeno v členu 5(2) PES, ni pa v preambuli nikjer sklica in

analize usklajenosti s členom 152(5), ki vsebuje konkretizacijo načela subsidiarnosti glede javnega zdravja na splošno in darovanja organov še posebej. Prav tako ni te podrobne analize v uvodni obrazložitvi. Priporočljivo bi bilo, da bi predlog vseboval med uvodnimi odstavki tudi poseben odstavek o skladnosti predloga s konkretnim načelom subsidiarnosti po členu 152 PES. Prav tako bi bilo priporočljivo, da bi posebej vseboval še razlago o odnosu člena 152(5) do predloga oz. med določbo člena 13 predloga do nacionalnih ureditev v smislu, da bi podrobneje razložil, na katere določbe nacionalnega pravnega reda držav članic člen 13 vpliva in na katere ne (prim. jasno razlago v 12. uvodnem odstavku Direktive 2004/23). Ker se uvodni odstavki uporabljajo kot razlagalni pripomoček pri uporabi sekundarne zakonodaje EU, bi priporočene spremembe bistveno izboljšale pravno določnost predloga.

Ne glede na navedene formalne (proceduralne) pripombe pa opisane pomanjkljivosti niso take, da bi načele materialno ustreznost predloga. Zato ZPS presoja, da predlog **upošteva** načelo subsidiarnosti.

Višji svetovalec III
mag. Samo Kutoš, l.r.

Božo Strle
vodja

V vednost:
- Odboru za zdravstvo

REPUBLIC OF SLOVENIA
NATIONAL ASSEMBLY
Committee on EU Affairs

No: 008-19/08-8/8
Date: 23 January 2009

Committee on EU Affairs

At its 7th meeting of 23 January 2009, discussing item 6 "Reasoned opinion regarding compliance with the principle of subsidiarity in 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", the Committee on EU Affairs adopted the following

DECISION:

Having regard to the opinion of the Committee on Health of 21 January 2009 and the opinion of the Legislative and Legal Service of 15 January 2009, the Committee on EU Affairs hereby establishes that 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* complies with the principle of subsidiarity as required by the *Protocol on the application of the principles of subsidiarity and proportionality* annexed to the *Treaty on European Union* and the *Treaty on the Functioning of the European Union*.

D. Lavtižar Bebler
Darja Lavtižar Bebler
Chair

Cc:
- Council of the President of the National Assembly
- Committee on Health

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REPUBLIC OF SLOVENIA
NATIONAL ASSEMBLY

Committee on Health

No:
Ljubljana: 21 January 2009

COMMITTEE ON EU AFFAIRS

By *mutatis mutandis* application of Article 154h(2) of the Rules of Procedure of the National Assembly of the Republic of Slovenia (Official Gazette of the Republic of Slovenia No. 35/2002, 60/2004, 64/2007), the Committee on Health - as the **working body responsible** - adopted the following

OPINION

regarding compliance with the principle of subsidiarity under the Protocol on the application of the principles of subsidiarity and proportionality annexed to the Treaty on European Union and the Treaty on the Functioning of the European Union, in 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

At its 4th meeting of 12 December 2008, the Committee on EU Affairs - discussing item 7 on the agenda - called upon the Committee on Health to deliver a reasoned opinion as to whether 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 complied with the principle of subsidiarity as required by the Protocol on the application of the principles of subsidiarity and proportionality annexed to the Treaty on European Union and the Treaty on the Functioning of the European Union.

The Committee on Health carried out a subsidiarity check in relation to the said proposal at its 1st regular meeting of 21 January 2009.

Mr. Matevž Frangež, Deputy Chair of the Committee on EU Affairs and initiator of the above procedure, explained that COSAC each year adopts a decision whereby all Member States' national parliaments carry out at least two subsidiarity checks per year on jointly selected draft legislative acts. Thus, at their meeting in Paris in July

2008, the committee chairmen decided to carry out a subsidiarity check on 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. The proposal was published in all EU official languages on 10 December 2008, together with an eight-week deadline to carry out the check. Such deadline is provided by the above Protocol on the application of the principles of subsidiarity and proportionality of the Lisbon Treaty. The implementation of the subsidiarity check for one of the "pilot projects" should anticipate the actual functioning and cooperation of parliaments in such area, particularly when the Lisbon Treaty will have entered into force.

Considering that the purpose of such checks is to increase the involvement of national parliaments in the preliminary procedure, in accordance with hitherto practice the Committee on EU Affairs decided at its 4th meeting of 12 December 2008 that the proposed Directive and the relevant materials prepared by the COSAC Secretariat be forwarded to the working body responsible - i.e. the Committee on Health - and to the Legislative and Legal Service, asking them to deliver reasoned opinions as to whether the proposal complies with the principle of subsidiarity as provided by the Protocol. Upon taking note of the opinion on the Committee on EU Affairs, its expert service will draw up a report to be sent to the COSAC Secretariat. Based on the reports received by the national parliaments, COSAC will hold a debate on possible violations of the principle of subsidiarity in the above proposal and on the success of the checks at its meeting in May 2009.

In the new institutional structure under the Lisbon Treaty, greater significance is attributed to Member States' national parliaments. In recent years, in fact, the complex issue of their involvement in EU decision-making has been constantly in the centre of discussions, mainly for two reasons. First, in relation to the increasing number of legislative acts adopted at Community level that need to be transposed into national legislations and, second, in relation to the constantly underlined "democratic deficit" on the side of EU institutions.

The new Article 12 of the Treaty on European Union points out that national parliaments contribute actively to the good functioning of the Union, particularly by seeing to it that the principle of subsidiarity is respected in accordance with the procedures provided for in the Protocol on the application of the principles of subsidiarity and proportionality. In accordance with the principle of subsidiarity " in areas which do not fall within its exclusive competence, the Community takes action only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States at the national, regional or local levels and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community". Ensuring the respect of such principle means preventing that the Union interferes in areas that are not within its competence but are left within the competence of the Member States.

Mr. Samo Kutoš from the Legislative and Legal Service drew up a written opinion in which he delivered a general definition of the principle of subsidiarity and proportionality and the Service's position on public health and subsidiarity and on subsidiarity in the proposed Directive. Despite certain concerns of, mainly, formal nature, the Legislative and Legal Service assessed that the proposal complied with the principle of subsidiarity.

An opinion on the proposed Directive was also delivered by the National Council, more precisely by the Commission for Social Care, Labour, Health and the Disabled and the Commission for International Relations and European Affairs. Their opinion was presented by Mr. Peter Požun, Member of the National Council. Both Commissions find that the standards of quality and safety of human organs intended for transplantation in Slovenia - based on the provisions of the Removal and Transplantation of Human Body Parts for the Purposes of Medical Treatment Act (Official Gazette of the Republic of Slovenia No.: 12/00, 61/07) and the related implementing regulations - are high. According to the Act, the competent non-profit national institution is the Institute for Transplantation of Organs and Tissues - Slovenia Transplant.

The Commissions further establish that Slovenia is one of Europe's advanced countries in such area and is actively involved in its development at the EU level. With 20 donors per million inhabitants it is also above the European average. Particular mention was made of Article 11 of the Directive dealing with reporting systems for serious adverse events and reactions, which is considered insufficiently defined in the sense of a basic uniformity of procedures applied in such events. For that reason it will not ensure the same level of security in all EU Member States. In Slovenia, such issue is very well regulated - special protocols on traceability of organs intended for transplantation were introduced on the basis of the law as early as 2000. Authorisation for exercising control was given to Slovenia Transplant which performs such function with due care and diligence. The National Council Commissions establish that the proposed Directive is not inconsistent with the principle of subsidiarity, yet call upon the Slovenian Government and the Ministry of Health to commit themselves in any further procedures regarding the proposal that Article 11 be reconsidered to better ensure the functioning of the reporting systems for serious adverse events and reactions.

According to the representative of the Ministry of Health Mr. Janez Remškar, the draft position of the Republic of Slovenia on the proposed Directive is underway and will be sent - based on the Act on Cooperation between the National Assembly and the Government regarding EU Affairs - to the National Assembly. Considering that legislation concerning the quality and safety of human organs intended for transplantation differs from country to country, coordination at the EU level would be recommended. The Ministry of Health assesses that the proposal complies with the principle of subsidiarity.

The members of the Committee stressed in the debate that considering all the presented opinions, the proposed Directive enshrines all the above principles. The issue under consideration is a highly sensitive issue where Slovenia has achieved remarkable results and its legislation is well developed.

Following the debate, the Committee on Health adopted the following opinion:

The Committee on Health establishes that 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 complies with the principle of

subsidiarity under the Protocol on the application of the principles of subsidiarity and proportionality annexed to the Treaty on European Union and the Treaty on the Functioning of the European Union.

The rapporteur at the meeting of the competent working body will be the member of the committee Mr. Anton Colarič.

Hedvika Stanič Igličar
Committee Secretary

Ljubo Germič
Chair

REPUBLIC OF SLOVENIA
NATIONAL ASSEMBLY
Legislative and Legal Service

No: 008-19/08-8/
Date: 15 January 2009

COMMITTEE ON EU AFFAIRS

Subject: Opinion regarding compliance with the principle of subsidiarity in 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

On 12 December 2008, the Legislative and Legal Service of the National Assembly of the Republic of Slovenia was called upon by the Committee on EU Affairs to prepare a reasoned opinion as to whether the proposed Directive (hereinafter: the proposal) complied with the principle of subsidiarity as required by the Protocol on the application of the principles of subsidiarity and proportionality (hereinafter: the Protocol), annexed to the Treaty on European Union and the Treaty establishing the European Community (TEC).

About the principle of subsidiarity and proportionality
The principle of subsidiarity and proportionality is enshrined in Article 5(2) of TEC; according thereto, in areas which do not fall within its exclusive competence, the Community takes action (e.g. adopts legislative acts) only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States at the national, regional or local levels (negative criterion or necessity test) and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community (positive criterion or value-added test). The positive and the negative criteria must be met cumulatively. The principle of subsidiarity is defined in the third paragraph of the same article: any action by the Community shall not go beyond what is necessary to achieve the objectives of the Treaties. The manner to apply (implement) such principle is defined in Article 5 of the Protocol: any draft legislative act should contain a detailed statement making it possible to appraise compliance with the principle of subsidiarity. This statement should contain some assessment of the proposal's financial impact. In the case of a directive, it should also contain information on the implications for the rules to be put in place by Member States. The reasons for concluding that a Union objective can be better achieved at Union level should be substantiated by qualitative and, wherever possible, quantitative indicators. Last but not least, Article 5 of the Protocol requires

that proposals should take account of the need for any financial or administrative burden to be minimised and commensurate with the objective to be achieved.
In addition to the general provision on the principle of subsidiarity enshrined in Article 5 of the TEC, this principle is further specified in the Treaty's provisions concerning specific fields, such as public health which is regulated in Title XIII of the TEC.

Public health and subsidiarity
The only article under Title XIII is Article 152. In paragraph 1, it provides that a high level of human health protection must be ensured in the definition and implementation of all Community policies and activities (known as *mainstreaming*). In the second and third subparagraphs of the same paragraph, particular emphasis is placed on the flight against the major health scourges and on the fight against drugs. The second subparagraph of paragraph 2 defines for the first time the principle of subsidiarity, providing that (primarily) Member States, in liaison with the Commission, coordinate among themselves their policies and programmes in the above areas. Paragraph 3 deals with international cooperation.
For the proposal under discussion, the most relevant paragraph is paragraph 4: point (a) thereof provides that in the codecision procedure under Article 251 of TEC, (legislative) measures are adopted, *inter alia*, that set high standards of quality and safety of organs and substances of human origin, blood and blood derivatives. Point (a) also includes a limitation in terms of subsidiarity, providing that these measures do not prevent any Member State from maintaining or introducing more stringent protective measures. An additional limitation in the sense of the principle of subsidiarity is found in paragraph 5 of Article 152, stating that Community action in the field of public health fully respects the responsibilities (i.e. competences) of the Member States for the organisation and delivery of health services and medical care. The specific limitation of Community competences is in the provision stating that measures referred to in paragraph 4(a) do not affect national provisions on the donation or medical use of organs and blood. The provisions of paragraphs 4(a) and 5 should be read together in order to make sense. An interpretation whereby paragraph 5 would exclude organ donation from EU regulations is not possible as it could literarily mean that the standards of quality referred to in paragraph 4(a) do not apply to the donation of organs. These provisions thus need to be read in the sense that the standards of quality adopted by the EU indeed apply also to the donation of organs. Other issues on organ donation that do not affect standards, however, remain within the competence of the Member States. In practice, this relates to, for example, admissibility of donation among relatives, form of consent (see below), etc.
Article 152(4)(a) already served as a basis for the adoption of Directive 2002/98 on blood and blood components and Directive 2004/23 on human tissues and cells, as well as certain implementing acts. The proposal under discussion also relates to the third field of Article 152(4)(a).

Subsidiarity in the proposal
The elements of the statement on subsidiarity and proportionality are indicated in the explanatory memorandum of the proposal. Data on the expected financial impacts of the proposal and the requirement to minimise costs are specified in the "Legislative financial statement"; the latter is - according to the Legislative and Legal Service -

appropriate. Particular attention is drawn to the fact that financial impacts are indicated in figures, thereby meeting the requirement for quantitative assessment.
The main part of the assessment of compliance with the principle of subsidiarity is the assessment of the negative and positive criteria, also known as comparative efficiency test, i.e. the assessment whether a Community objective is better achieved at Community level rather than at national level. The fulfilment of criteria is a topic dealt with under the section "The added value of the Directive", assessing the fulfilment of, in particular, the positive criterion. Particularly important is the last part of the section "Facilitating cooperation between Member States and cross-border exchanges": paragraph 27 contains the objective of ensuring a high level of quality and safety throughout the 'organ transplantation chain' in *all* Member States, bearing in mind the freedom of movement of citizens and the need to enhance the cross-border exchange of organs. This should convince the European citizens that the same standards as those in their own country apply in all Member States. The necessity of cross-border exchange is justified in paragraph 28 by the fact that to cover the needs of all the patients on the waiting lists, a large donor pool is important, particularly for the most sensitive patients. Paragraphs 29-31 explain the mechanisms whereby the proposal achieves such objectives. Particular mention needs to be made of paragraph 24 of the explanatory memorandum, explicitly stating - in accordance with subsidiarity - that the proposed Directive does not deal with certain sensitive ethical issues concerning the consent for organ donation.
To the opinion of the Legislative and Legal Service, the explanatory memorandum in principle complies with the requirement for explaining the proposal in terms of subsidiarity. Likewise, subsidiarity is observed in the provisions referring to transnational elements of organ transplantation within the EU in accordance with the proposal's objectives. Chapter II of the proposal deals with organisations and procedures (procurement, traceability, transport, reporting, etc.) which should ensure standards of quality and safety as defined in more detail in Chapter III. The exchanges of information among the Member States and with third countries are regulated by Chapter IV and V, respectively. Chapter VI (General Provisions) contains the same provisions ad most directives. Thus, the proposal contains mainly provisions that are obviously intended to establish the same standards of quality and safety in all Member States, which is indeed in line with Article 152(4)(a).
The Legislative and Legal Service assesses that the regulation of organ donation in the proposal needs more consideration. As stated above, Article 152(5) explicitly prohibits that EU legislative measures affect national provisions on the donation of organs. In such context, attention needs to be drawn to Articles 13 and 14 of the proposal that - apparently contrary to the said provision - regulate the donation of organs. Article 13 contains - as indicated by the title - principles governing organ donation, whereby Member States must ensure that donations of human organs from deceased and living donors are voluntary and unpaid (paragraph 1), that advertising organ donation for financial gain is prohibited (paragraph 2), and that procurement of organs is carried out on a non-profit basis (paragraph 3). Pursuant to Article 14, procurement may only be carried out after compliance with all mandatory consent or authorisation requirements in force in the Member State concerned. This second provision is drawn up so that it does not prejudice the competence of the Member State, linking procurement explicitly to *national* requirements and conditions instead of those posed by the Directive as such. Therefore, Article 14 does not prejudice the competences of the Member States.

An outstanding issue is, however, whether the mandatorily unpaid and non-profit organ donation provided by Article 13 interferes with the prohibition of regulating donation pursuant to paragraph 5 as explained above. The issue arises in particular in relation to a similar provision enshrined in Directive 2004/23 on blood and blood components: Article 12(1) thereof stipulates that Members States merely "endeavour" to ensure unpaid donations of blood. The second subparagraph of Article 12(1) provides for the possibility of compensations in certain cases. On the contrary, Article 13 of the proposal *commits* the Member States to unpaid donations.

As a reply to any such concern, the Legislative and Legal Service points out that the very significance of the term "donation" excludes the possibility of financial gain as this would instead mean "trading". Likewise, it underlines one of the basic principles of EU law, namely that the Union is committed to the respect of human rights as deriving from constitutional traditions of the Member States and human rights' treaties. This principle has been pursued by the European Court of Justice ever since the *Nold v. Commission* case (1974 ECR 491). Furthermore, it draws attention to Article 6 of the TEU which reiterates the principle from the *Nold* ruling (paragraph 1) and explicitly refers to the European Convention on Human Rights (paragraph 2). The Convention has been signed by all EU Member States, which means that it is a part of their "domestic" law. In terms of the proposed Directive, particularly important is paragraph 16 of the preamble referring to the Convention on Human Rights and Biomedicine. The latter is based on the European Convention on Human Rights, which means that it is also subject to Article 6(2) of the TEU. According to paragraph 16, the said Convention explicitly requires voluntary and unpaid donation. In more detail, this issue is regulated by Article 21 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning the transplantation of organs and tissues of human origin. According to paragraph 1 thereof, the human body and its parts (i.e. also organs) should not give rise to financial gain. Although its second sentence allows the possibility of compensation, this only applies for loss of earnings and expenses and not for donation. Paragraph 2 of the same Article prohibits advertising with a view of financial gain. The provision of Article 13 of the proposed Directive thus complies, *mutatis mutandis*, with the provision of Article 21 of the Additional Protocol. Since the latter - based on Article 6(2) of the TEU and the above Court ruling - is a part of EU and Member States' law in terms of protection of human rights, the prohibition under Article 13 merely reiterates a norm already existing in Member States' law; therefore, it does not prejudice their competences contrary to the principle of subsidiarity.

Likewise important is the reference to the EU Charter of Fundamental Rights in paragraph 16 of the preamble. Similarly to the Additional Protocol, the third indent of Article 3(2) of the Charter prohibits making the human body and its parts a source of financial gain. Given the failed ratification of the Treaty Establishing the Constitution for Europe and the unfinished ratification of the Lisbon treaty, however, the Charter is not a legally binding act. Nevertheless, in the Case C-540/03 (*European Parliament v. Council* [2006] ECR I-5769) the European Court stressed that the Charter recognises human rights as resulting from the constitutional traditions common to the Member States, from the treaties and legal acts under primary or secondary Community law, conferring the latter the power of interpretation in establishing which norms on human rights constitute a part of Community law. Since the non-profit use of the human body and its parts, including organs, is enshrined in the Charter, the principle of non-profitability is also a constituent part of Community law and needs to be respected by the Member States.

The Legal and Legislative Service thus assesses that in terms of content Article 13 is not in contravention of the principle of subsidiarity, yet in order to satisfy formal (procedural) requirements more properly, the proposal could contain a more detailed and explicit explanation of the issues under consideration. Paragraph 23 of the preamble does feature a general reference to the principle of subsidiarity, as provided by Article 5(2) of the TEC, but contains no reference to or analysis of compliance with Article 152(5) specifying subsidiarity in public health and, more precisely, organ donation. Likewise, no such analysis is found in the explanatory memorandum. It would be recommended the proposal contained - among the initial paragraphs - a special paragraph on the proposal's compliance with the principle of subsidiarity under Article 152 of the TEC. It would be likewise recommended that it contained, in addition, an interpretation of the relation between Article 152(5) and the proposal, namely between Article 13 of the proposal and individual national provisions in the sense of explaining in more detail which Member States' national provisions are affected by Article 13 and which are not (comp. the interpretation in paragraph 12 of the preamble of Directive 2004/23). Since the preamble is used as an interpreting tool for applying EU secondary legislation, the above recommended modifications could significantly improve the legal clarity of the proposal.
Notwithstanding the above formal (procedural) comments, the mentioned drawbacks are not such that they could undermine the substantial adequacy of the proposal. The Legislative and Legal Service thus assesses that the proposal **complies** with the principle of subsidiarity.

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- Committee on Health