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SVAR PÅ UDVALGSSPØRGSMÅL

Patientrettigheder

Til underretning for Folketingets Europaudvalg vedlægges Ministeriet for Sundhed og Forebyggelses besvarelse af spørgsmål nr. 1 og 2 ad KOM (2008) 0414 af den 9. oktober 2009 om forslag til Europa-Parlamentets og Rådets direktiv om patientrettigheder i forbindelse med grænseoverskridende sundhedsydelser.

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Dato:
Sags nr.: 0907942
Sagsbeh.: hcf
Dok nr.: 118477

Folketingets Europaudvalg har den 9. oktober 2009 stillet følgende spørgsmål nr. 1 (Alm. del) til udenrigsministeren, som hermed besvares. Spørgsmålet er stillet efter ønske fra Lone Dybkjær (RV).

KOM (2008) 0414
Forslag til Europa-Parlamentets og Rådets direktiv om patientrettigheder i forbindelse med grænseoverskridende sundhedsydelser

Spørgsmål nr. 1:

''Ministeren bedes - som lovet på Europaudvalgets møde den 2. oktober 2009 - oversende det kompromisforslag, som er fremsat i forhandlingerne om direktivet om patientrettigheder i forbindelse med grænseoverskridende sundhedsydelser (KOM (2008) 414). Ministeren bedes eksemplificere, hvad kompromisforslaget konkret vil betyde for behandlingsmulighederne for en patient med en 'almindelig lidelse'. Ministeren bedes desuden fremsende et notat, der beskriver, hvilke dele af dette kompromisforslag, som regeringen kan acceptere, og hvilke dele regeringen ikke kan acceptere."

Svar:

Til udvalgets orientering fremsender jeg hermed som ønsket det kompromisforslag af 31. juli 2009, som er fremsat af det svenske formandskab i forhandlingerne om direktivet om patientrettigheder i forbindelse med grænseoverskridende sundhedsydelser – KOM (2008) 414.

Jeg henviser desuden til vedlagte notat om status for forhandlingerne om direktivforslaget, som samtidig vil kunne danne grundlag for min drøftelse med udvalget den 28. oktober 2009.

I notatet gennemgås hovedelementerne i det svenske formandskabs kompromisforslag set i forhold til det oprindelige forslag fra Kommissionen. Med henblik på besvarelse af udvalgets spørgsmål 1 redegøres der i notatet samtidig for, hvilke dele af kompromisforslaget regeringen kan acceptere og hvilke dele regeringen ikke kan acceptere (afsnit 11). Der er endvidere givet en række eksempler på, hvad direktivet konkret vil betyde for patienter med en "almindelig lidelse" (afsnit 9).

Med venlig hilsen

Jakob Axel Nielsen / Hanne Findsen

Ministeriet for Sundhed og Forebyggelse
Dato: 15. oktober
Sagsnr.: 0900829/0907942
Sagsbeh.: hcf
Dok nr: 114692

Notat til Folketingets Europaudvalg om status for forhandlingerne om direktivforslaget vedrørende patientrettigheder i forbindelse med grænseoverskridende sundhedsydelser

Nedenfor redegøres for status i forhandlingerne om direktivforslaget vedrørende patientrettigheder i forbindelse med grænseoverskridende sundhedsydelser – KOM (2008) 414.

Notatet baserer sig på formandskabets kompromisforslag af 31. juli 2009, som fortsat drøftes på arbejdsgruppeniveau. Formandskabet har under drøftelserne forelagt nye udkast til udvalgte bestemmelser med henblik på at kunne forelægge et samlet revideret kompromisforslag. Dette reviderede kompromisforslag ventes præsenteret inden udgangen af oktober og vil danne grundlag for de videre drøftelser frem mod rådsmødet (beskæftigelse, socialpolitik, sundhed og forbrugerbeskyttelse) den 1. december 2009, hvor formandskabet sigter efter at opnå politisk enighed.

Det skal således understreges, at der fortsat vil kunne forekomme justeringer af de skitserede løsninger. Det er dog regeringens forventning, at det endelige resultat af Rådets førstebehandling af direktivet i det væsentlige vil kunne baseres på det foreliggende kompromisforslag.

Europaudvalget vil i forbindelse med forelæggelsen af rådsmødet den 1. december blive orienteret om status i forhandlingerne og herunder om eventuelle ændringer i kompromisforslaget af betydning i forhold til de danske synspunkter.

1. Generelt om baggrunden for Kommissionens forslag

EF-Domstolen har i en række domme afsagt siden 1998 fastslået, at en sundhedsydelse modtaget i et andet EU-land er en tjenesteydelse i EF-traktatens forstand og derfor omfattet af EF-traktatens regler om fri bevægelighed, herunder artikel 49 om fri bevægelighed for tjenesteydelser.

Eventuelle begrænsninger i den frie udveksling af sundhedstjenesteydelser skal kunne begrundes i tvingende almene hensyn og må ikke overskride, hvad der er objektivt nødvendigt med henblik på formålet, og det samme resultat må ikke kunne opnås med mindre indgribende regler.

Domstolen har endvidere fastslået, at visse objektive hensyn efter omstændighederne kan retfærdiggøre en begrænsning af den frie udveksling af sundhedstjenesteydelser:

- beskyttelse af folkesundheden, herunder opretholdelse af et stabilt læge- og hospitalsvæsen, som alle har adgang til, og som bidrager til et højt niveau for beskyttelse af sundheden ved opretholdelse af behandlingsmuligheder eller en

lægelig kompetence på sundhedsområdet eller en lægelig kompetence på det nationale område,

- risikoen for et alvorligt indgreb i sundhedsvæsenets økonomiske balance, såfremt det overordnede niveau for beskyttelse af den offentlige sundhed påvirkes.

Kommissionen fremsatte i juli 2008 sit direktivforslag om patientrettigheder i forbindelse med grænseoverskridende sundhedsydelser. Hovedformålet med forslaget er at omsætte Domstolens praksis i en klar retlig ramme for grænseoverskridende sundhedsydelser i EU.

2. Afgræsning af omfattede sundhedsydelser

Generelt
Retten til betalt behandling i en anden medlemsstat er efter artikel 6 i Kommissionens oprindelige forslag afgrænset til at omfatte de ydelser, som patienten har ret til i sit hjemland. Udgifterne til behandling i en anden medlemsstat refunderes af patientens hjemland med et beløb, der svarer til, hvad hjemlandet skulle have betalt for behandlingen, hvis den var ydet af hjemlandet sundhedssystem. Dog kan refusionen ikke overstige de faktiske omkostninger ved den modtagne behandling.

Direktivet giver med andre ord ikke patienterne ret til at få refunderet udgifter for en behandling i en anden medlemsstat, som de ikke i forvejen ville have ret til at få i deres hjemland. Det vil heller ikke være muligt for patienterne at "tjene" på at blive behandlet i et andet medlemsland.

Der er bred enighed blandt medlemsstaterne om disse grundlæggende principper, som baserer sig på EF-domstolens praksis, og som også er fastholdt i det seneste kompromisforslag fra formandskabet.

Medicintilskud
Kommissionens oprindelige forslag gav ikke klarhed om, hvorvidt medicintilskud var omfattet af direktivforslaget eller ej. Enkelte lande, og heriblandt Danmark, har under forhandlingerne af patientsikkerhedsmæssige hensyn argumenteret for, at tilskud til medicin ikke bør være omfattet af forslaget. Det fremgår imidlertid nu eksplicit af den foreliggende tekst, at tilskud til lægemidler og medicinsk udstyr er omfattet af forslaget.

En vedtagelse af direktivforslaget i den foreliggende form vil derfor indebære, at Danmark fremover skal refundere udgifter til medicin, som dansk sikrede har købt på et apotek i et andet EU-land og til medicin købt i Danmark på baggrund af en udenlandsk recept, jf. nedenfor i punkt 8 om gensidig anerkendelse af recepter.

Omfanget af medicinhandel på udenlandske apoteker som følge af forslaget er vanskeligt at opgøre. Det er regeringens vurdering, at handlen langt overvejende vil ske via internettet. Det vil formentlig især være kronikere i fast medicinering, der for at opnå en billigere pris vælger at sende deres recept til et udenlandsk apotek, og herefter få medicinen fremsendt. På den baggrund – og med henvisning til at udenlandske apoteker også er underlagt en national sikkerhedskontrol – vurderes sikkerhedsrisikoen for danske borgere at være begrænset.

Samtidig skal det understreges, at der kun vil være tilskud til medicin, som i forvejen er tilskudsberettiget i Danmark.

3. Mulighed for om nødvendigt og inden for Traktatens rammer at afvise patienter fra andre medlemsstater til planlagt behandling

Det følger af artikel 5 i Kommissionens oprindelige forslag, at patienter fra andre medlemsstater skal behandles på samme måde som behandlingsmedlemsstatens egne borgere, og at medlemsstaterne skal overholde princippet om ikke-forskelsbehandling. Det fremgår samtidig af forslagets indledende betragtninger, at direktivet dog ikke indebærer, at " sundhedstjenesteydere skal acceptere planlagt behandling eller give førsteret til patienter fra andre medlemsstater til skade for andre patienter med lignende sundhedsbehov, f.eks. ved at øge ventetiden på behandling."

Formuleringen må tolkes således, at udenlandske patienter kan komme foran danske patienter f.eks. på en venteliste til operation i tilfælde af, at den udenlandske patients tilstand inden for samme sygdomskategori er dårligere end den danske patients.

Det fremgår fortsat af kompromisforslaget, at patienter fra andre medlemsstater skal nyde samme rettigheder som hjemlandets egne patienter. Til gengæld er det nu i kompromisforslaget fastlagt, at medlemsstaterne har mulighed for – hvor det er begrundet i overordnede og almene hensyn – at træffe foranstaltninger vedrørende adgangen til sundhedsydelser med henblik på at opfylde deres grundlæggende ansvar med hensyn til at sikre tilstrækkelig og permanent behandlingskapacitet i de nationale sundhedssystemer. Sådanne foranstaltninger skal begrænses til, hvad det er nødvendigt og proportionalt og må ikke indebære diskrimination.

Det er vurderingen, at man fra dansk side med disse bestemmelser vil kunne begrænse adgangen af patienter fra andre EU-lande, som søger behandling på offentlige hospitaler her i landet i mindst samme omfang, som de offentlige hospitaler i dag efter gældende danske ret kan afvise danske fritvalgspatienter fra andre regioner af kapacitetsmæssige hensyn, herunder af hensyn til at de højt specialiserede sygehusafdelinger først og fremmest skal anvende deres kapacitet til patienter med behov for deres ekspertise.

I dag kan regionerne ikke efter dansk lovgivning modtage selvbetalere, herunder fra andre lande. Implementeringen af direktivet vil således kræve en ændring af lovgivningen på dette punkt.

4. Kvalitets- og sikkerhedsstandarder samt klage og erstatningsmuligheder

Artikel 5 i Kommissionens oprindelige forslag indeholdt en række krav til medlemsstaterne om fastsættelse af kvalitets- og sikkerhedsstandarder for sundhedsydelser i de nationale sundhedssystemer, krav om overholdelse og overvågning af sådanne standarder, krav om informeret samtykke fra patienterne samt krav om, at patienterne sikres klageadgang og erstatningsmuligheder. Der blev desuden lagt op til, at Kommissionen i samarbejde med medlemsstaterne kunne udarbejde retningslinjer for at fremme gennemførelsen af disse krav.

Under forhandlingerne er der blandt andet fra dansk side stillet spørgsmålstegn ved, om den foreslåede bestemmelse lå inden for rammerne af Fællesskabets beføjelser i henhold til Traktaten.

Artikel 5 er i det foreliggende kompromisforslag ændret væsentligt, idet der for så vidt angår kvalitet og sikkerhed nu alene er tale om informationskrav. Endvidere lægges der ikke længere op til, at Kommissionen i samarbejde med medlemsstaterne kan fastsætte fælles retningslinjer vedrørende kvalitet og sikkerhedsstandarder mv. Bestemmelsen indeholder dog fortsat krav til medlemsstaterne om at sikre klageadgang, journalindsigt, mulighed for at søge erstatning samt et nyt element vedrørende krav om gennemsigtighed i fastsættelsen af takster for patienter fra andre medlemsstater.

Det må overvejes om et eventuelt krav om gennemsigtighed i prisfastsættelsen, således at priser skal fastsættes ud fra objektive, ikke-diskriminerende kriterier skal indarbejdes i sundhedslovgivningen, da dette ikke i dag er reguleret for så vidt angår private patienter og private klinikker m.v.

5. Forhåndsgodkendelse til hospitalsbehandling og højt specialiseret ikke-hospitalsbehandling

Spørgsmålet om forhåndsgodkendelse har været et centralt element i forhandlingerne om direktivforslaget.

For det første har det været drøftet, om medlemsstaterne generelt – eller kun i konkrete situationer, f.eks. hvor den økonomiske balance i sundhedsvæsenet er truet – kan stille krav om forhåndsgodkendelse til hospitalsbehandling og højt specialiseret behandling.

For det andet har det været et centralt spørgsmål at få afklaret, hvilke sundhedsydelser der i givet fald kan omfattes af et krav om forhåndsgodkendelse. EF-domstolen har fastslået, at der ikke kan stilles krav om forhåndsgodkendelse til ikke-hospitalsbehandling, men der kan ikke heraf udledes nogen fælles definitioner af, hvad der forstås ved "hospitalsbehandling" og "ikke-hospitalsbehandling".

Medlemsstaternes adgang til at stille krav om forhåndsgodkendelse
Regler om forhåndsgodkendelse skal efter EF-Domstolens praksis blandt andet være proportionale i forhold til formålene, og en forhåndsgodkendelsesordning skal bygge på objektive, saglige og på forhånd fastlagte kriterier.

For så vidt angår hospitalsbehandling har Domstolen i de hidtidige sager fastslået, at en person med ret til hospitalsbehandling i sit hjemland kan få refusion i hjemlandet for denne behandling i en anden medlemsstat, hvis vedkommende har fået forhåndsgodkendelse gennem sit eget system. Forhåndsgodkendelse *skal* gives, hvis sundhedsvæsenet i patientens hjemland ikke kan yde den pågældende behandling rettidigt, dvs. inden for en lægefagligt forsvarlig tidsfrist.

I Kommissionens oprindelige forslag var der ikke lagt op til, at medlemsstaterne kunne indføre en generel ordning med krav om forhåndsgodkendelse til hospitalsbehandling. Derimod skulle et eventuelt krav om forhåndsgodkendelse efter forslagets artikel 8 være begrænset til konkrete situationer, hvor en udstrømning af patienter som følge af direktivet griber alvorligt ind i – eller formentlig griber alvorligt

ind i – den økonomiske ligevægt i den nationale sikringsordning og/eller planlægning og rationalisering i hospitalssektoren.

Et bredt flertal blandt medlemsstaterne har under forhandlingerne problematiseret denne del af Kommissionens forslag med henvisning til, at det af planlægnings- og styringsmæssige årsager er nødvendigt at kunne fastholde et generelt krav om forhåndsgodkendelse til hospitalsbehandling og højt specialiseret behandling.

I formandskabets kompromisforslag er det nu blevet præciseret, at medlemsstaterne generelt kan stille krav om forhåndsgodkendelse til behandling, som er genstand for planlægning i det omfang den

- involverer mindst én overnatning,
- kræver brug af højt specialiseret og omkostningstung medicinsk infrastruktur eller udstyr eller
- indebærer en særlig sundhedsrisiko for patienten eller for befolkningen

Endvidere fastslås det eksplicit i kompromisforslaget, at medlemsstaterne kan afslå at give forhåndstilladelse, hvis den pågældende behandling kan ydes rettidigt i hjemlandets system, dvs. inden for en lægefagligt forsvarlig tidsfrist.

Sondringen mellem hospitals- og ikke hospitalsbehandling
Domstolens sondring mellem hospitals- og ikke-hospitalsbehandling beror angiveligt på, at hospitalsbehandling er særligt udgiftstung og planlægningskrævende, og at det derfor på dette område er berettiget at beskytte medlemslandenes udgiftsniveau, investeringer og muligheder for at planlægge. Krav om forhåndsgodkendelse accepteres derfor af Domstolen med hensyn til hospitalsbehandling, men der findes som nævnt ingen fælles definitioner af, hvad der forstås ved "hospitalsbehandling".

Imidlertid kan behandling uden for hospital også i visse tilfælde være særdeles planlægningskrævende og forudsætte store investeringer. Det gælder for eksempel scanninger. Der kan derfor også for så vidt angår ikke-hospitalsbehandling være objektive hensyn, der kan retfærdiggøre en begrænsning af den frie udveksling af sundhedstjenesteydelser, dvs. hvor der også bør kunne stilles krav om forhåndstilladelse.

På den baggrund lagde Kommissionen i sit oprindelige forslag op til, at der laves en *fælles* liste over behandling, som f.eks. kræver brug af højt specialiseret og omkostningskrævende udstyr og som dermed også kunne omfattes af et krav om forhåndsgodkendelse.

Kommissionens forslag om en fælles liste har imidlertid ikke vundet støtte i Rådet. Et bredt flertal blandt medlemsstaterne har påpeget, at det er forskelligt fra land til land, hvordan behandlingen er tilrettelagt og at man derfor ønsker en model, hvor det overlades til medlemsstaterne at afgøre, hvilke sundhedsydelser der kategoriseres som højt specialiserede og dermed kan omfattes af forhåndsgodkendelsesordningen.

I formandskabets kompromisforslag er der i stedet lagt op til, at den enkelte medlemsstat selv skal offentliggøre, hvilke sundhedsydelser den vil lade omfatte af kravet om forhåndsgodkendelse samt information om forhåndsgodkendelsessystemet som sådan.

Konsekvenser for danske patienters adgang til hospitalsbehandling i andre EU-lande
Reglerne om patienters adgang til hospitalsbehandling i andre medlemsstater i henhold til EF-retten findes i bekendtgørelse nr. 594 af 11. juni 2009 om ret til hospitalsbehandling m.v., EF-forordning 1408/71 om social sikring af vandrende arbejdstagere mv. og vejledning til patienterne af 7. november 2008 om dækning af hospitalsbehandling i andre EU- og EØS-lande.

Det følger af bekendtgørelsen, at patientens bopælsregion skal give forhåndstilladelse til hospitalsbehandling i andre EU-lande, hvis bopælsregionen ikke kan tilbyde rettidig behandling på egne sygehuse, andre offentlige sygehuse, samarbejdssygehuse eller aftalesygehuse i forhold til patientens behandlingsbehov. Det fremgår endvidere, at forhåndstilladelsen kun kan dække samme eller tilsvarende behandling, som patienten ville være tilbudt her i landet. Disse kriterier for forhåndsgodkendelse vil også være gældende efter EF-forordning 883/2004 om koordinering af de sociale sikringsordninger, der afløser EF-forordning 1408/71 formentlig pr. 1. maj 2010.

På den baggrund vurderes direktivet ikke i den foreliggende form at ville indebære ændringer i forhold til den adgang danske patienter i forvejen gives i henhold til EF-retten med hensyn til at få refunderet udgifter til hospitalsbehandling og højtspecialiseret ikke-hospitalsbehandling i andre medlemsstater.

Nedenfor i afsnit 9 gives konkrete eksempler på direktivets forventede konsekvenser for danske patienter med en "almindelig" lidelse.

6. Tilmeldingsbaseret tilskudssystem for almenlægehjælp til gruppe 1-sikrede

Artikel 7 i Kommissionens oprindelige forslag fastslår i overensstemmelse med EF-Domstolens praksis, at der ikke kan kræves forhåndsgodkendelse til godtgørelse af udgifter til sundhedsydelser, som ikke kræver hospitalsindlæggelse. Samtidig følger det af forslagets artikel 6, at medlemsstaterne kan fastsætte de samme betingelser, behandlingskriterier og lovgivningsmæssige og administrative formaliteter for brug af sundhedsydelser i en anden medlemsstat, som dem der gælder, hvis patienten behandles i hjemlandet. Det kunne f.eks. være et krav om, at patienterne skal konsultere en alment praktiserende læge, før der kan søges specialiseret behandling. Det er dog en forudsætning, at sådanne nationale krav og betingelser ikke er diskriminerende eller udgør en hindring for den fri bevægelighed.

Det har under forhandlingerne i Rådet været uklart, i hvilket omfang disse bestemmelser kan rumme det danske tilmeldingsbaserede tilskudssystem, hvor den vederlagsfrie adgang til almen lægehjælp er betinget af, at patienten opsøger sin egen læge i Danmark, og hvor behandling hos en speciallæge forudsætter en henvisning, ligeledes fra patientens egen læge i Danmark.

I det foreliggende kompromisforslag er der foretaget en række justeringer, således at det nu fremgår, at medlemsstaterne har mulighed for at foretage en vurdering i det hjemlige sundhedssystem, hvis det er nødvendigt for at fastslå den individuelle patients ret til behandling. Det er dog fortsat usikkert, om denne ordlyd er dækkende i forhold til en generel, tilmeldingsbaseret tilskudsordning som den danske, eller om der alene lægges op til, at der om nødvendigt kan foretages en konkret vurdering i individuelle tilfælde. Endvidere kan det give anledning til tvivl, om det eks-

plicitte krav om at de nationale ordninger ikke må være diskriminerende og ikke må udgøre en uberettiget hindring for den fri bevægelighed, indebærer en indskrænkning i det råderum medlemsstaterne i dag har i henhold til EF-traktaten.

Det kan på den baggrund ikke udelukkes, at der med direktivet vil blive åbnet for, at danske gruppe 1-sikrede kan få tilskud til almen lægehjælp i andre medlemsstater og at en henvisning fra den udenlandske alment praktiserende læge til speciallæge vil kunne anvendes såvel i Danmark som i udlandet.

Det bemærkes i den forbindelse, at det allerede i dag er muligt for gruppe 1-sikrede at få tilskud til speciallægebehandling i andre medlemsstater, men at dette efter de nuværende danske regler forudsætter henvisning fra patientens egen læge i Danmark.

Samtidig er det forventningen, at danske patienter i givet fald kun i meget begrænset omfang vil benytte en eventuel mulighed for at få tilskud til almen lægehjælp i andre medlemsstater, dels fordi det må forventes at være forbundet med en vis egenbetaling og transport, dels fordi patienten kan få samme ydelse vederlagsfrit hos sin egen læge i Danmark.

7. Patienters udlæg

Generelt
Kommissionens oprindelige forslag indebærer i overensstemmelse med EF-Domstolens praksis, at en patient, som søger behandling i en anden medlemsstat efter direktivets regler, selv skal betale udgifterne for behandlingen i udlandet. Patienten kan efterfølgende helt eller delvist få refunderet udgiften svarende til det beløb, som samme behandling ville have kostet i hjemlandet eller det tilskud som ville være givet til samme behandling i hjemlandet. En eventuel difference skal patienten selv betale.

I debatten om Kommissionens forslag er det blandt andet fra Europa-Parlamentets side blevet påpeget, at en sådan ordning vil være mest fordelagtig for de patienter, som har råd til at lægge ud for behandlingen.

På den baggrund er der indsat en præambelbetragtning i formandskabets kompromisforslag, som understreger medlemsstaternes mulighed for på frivillig basis at stille egne patienter bedre end det minimumsniveau, som fastsættes med direktivet og herunder f.eks. at indføre en ordning med direkte afregning mellem myndighederne i hjemlandet og behandlingslandet. Det vil være op til medlemsstaterne at beslutte, om de vil gøre brug af denne mulighed.

En vedtagelse af direktivet i den foreliggende form vil ikke i sig selv indebære ændringer for danske patienter i relation til spørgsmålet om udlæg.

Der vil fortsat være tre "veje" til planlagt hospitalsbehandling i en anden medlemsstat:

- Danske patienter, som – efter de danske regler om det udvidede frie sygehusvalg, om maksimale ventetider for patienter med livstruende sygdomme og om højt specialiseret behandling i udlandet – opfylder betingelserne for at vælge vederlagsfri behandling i udlandet, herunder i andre EU-lande, vil fortsat kunne modtage behandlingen vederlagsfrit og uden selv at lægge penge ud.

- Danske patienter, som ikke kan tilbydes rettidig behandling i Danmark i forhold til deres behandlingsbehov vil have ret til

    - forhåndsgodkendelse til behandling på et *offentligt* sygehus i et andet EU-land efter reglerne i EF-forordning 883/04 (i dag forordning 1408/71). I disse tilfælde afregnes udgifterne direkte mellem landenes myndigheder, og patienten kan alene komme til at betale en typisk mindre egenbetaling.

    - forhåndshåndsgodkendelse af refusion af deres udgifter til behandling på et *offentligt eller privat* sygehus efter EF-domstolens retspraksis, som er gennemført i dansk ret. I disse tilfælde skal patienten selv lægge ud for behandlingen. Danmark vil efter direktivforslaget kunne bestemme, at danske patienter fortsat selv skal lægge ud for behandlingen, og at refusion heraf fortsat er betinget af en forhåndsgodkendelse. Patienten kan som i dag alene komme til at betale differencen mellem prisen på behandlingen i udlandet og DRG-taksten.

Patienter, som ønsker at blive behandlet på et privathospital i en anden medlemsstat, som ikke har aftale med det danske sundhedsvæsen, vil – som i dag – selv skulle lægge et typisk større beløb ud for behandlingen. Det vil derfor især være disse patienter, som ville kunne få glæde af en eventuel ordning, hvor afregningen skete direkte mellem hjemlandets myndigheder og privathospitalet i den anden medlemsstat.

For så vidt angår ydelser, der ikke er hospitalsbehandling, typisk ydelser i praksissektoren, f.eks. speciallæge- eller tandlægebehandling, må danske patienter fortsat selv lægge ud for ydelser modtaget i udlandet. Efterfølgende kan regionen/kommunen anmodes om refusion af de afholdte udgifter svarende til det tilskud/den takst, der ville være givet, hvis behandlingen var leveret ved en praktiserende speciallæge eller tandlæge i Danmark.

Dog vil reglerne i EF-forordning 883/04 om ret til en forhåndsgodkendelse i tilfælde, hvor en behandling ikke kan tilbydes rettidigt i Danmark, også kunne anvendes vedrørende ydelser, der ikke er hospitalsbehandling.

Fastsættelse af det beløb som danske patienter kan få refunderet
Direktivet fastlægger, at patienter, som opfylder betingelserne for en forhåndsgodkendelse til hospitalsbehandling og højt specialiseret behandling, kan få refunderet et beløb svarende det beløb, som samme behandling ville have kostet i hjemlandet. En eventuel difference skal patienten selv betale. I Danmark refunderes i dag et beløb svarende til DRG-taksten, som er den takst, som regionerne afregner indbyrdes, når de behandler hinandens patienter.

For så vidt angår ydelser i praksissektoren og visse kommunale sundhedsydelser refunderes efter gældende danske regler et beløb, der svarer til det tilskud eller den takst, der gives, hvis ydelsen var leveret her i landet, jf. sundhedslovgivningen eller overenskomster indgået i medfør heraf.

For så vidt angår almen lægehjælp til gruppe 1-sikrede, som ydes vederlagsfrit for patienten ved egen læge i Danmark, vil tilskuddet ved modtagelse af almen lægehjælp i en anden medlemsstat – såfremt dette bliver resultatet i det endelige direktiv – derfor blive fastlagt svarende til taksten for en tilsvarende ydelse, når den

gives i Danmark, jf. overenskomsten om almen lægegerning mellem Praktiserende Lægers Organisation og Regionernes Lønnings- og Takstnævn.

8. Forslagets kapitel IV om samarbejde mellem de nationale sundhedssystemer

Gensidig anerkendelse af recepter
Artikel 14 i Kommissionens oprindelige forslag indebærer, at danske apoteker forpligtes til at anerkende og ekspedere recepter, der er udstedt i et andet EU-land, hvis det pågældende lægemiddel er godkendt til at blive markedsført i Danmark. Begrænsninger på anerkendelse af individuelle recepter er ikke tilladt, medmindre de er begrænset til, hvad der er nødvendigt for og rimeligt af hensyn til folkesundheden, og ikke udgør et middel til forskelsbehandling eller er baseret på en legitim og begrundet tvivl om ægtheden eller indholdet af recepten.

Kommissionen vedtager i komitologiprocedure tiltag, der gør det muligt for en farmaceut eller anden sundhedsprofessionel at bekræfte ægtheden af recepten, og om recepten er udstedt af en autoriseret person.

Bestemmelsen om gensidig anerkendelse af recepter er med enkelte justeringer fastholdt i formandskabets kompromisforslag og vurderes at ville indgå i et samlet kompromis i Rådet.

I dag anerkender danske apoteker som hovedregel ikke recepter fra andre lande, fordi receptens ægthed ikke kan verificeres. Dog anerkendes recepter udstedt i de andre nordiske lande. En vedtagelse af direktivet i den foreliggende form, vil derfor indebære en ændring af de gældende danske regler på dette punkt.

Da der som nævnt lægges op til, at Kommissionen i komitologiprocedure fastsætter nærmere regler og retningslinjer med henblik på at sikre de fornødne kontrolmekanismer, vurderes forslaget at imødekomme det danske synspunkt om, at gensidig receptanerkendelse forudsætter etablering af en række kontrolmekanismer.

Der henvises i øvrigt til Ministeriet for Sundhed og Forebyggelses notat til Folketingets Europaudvalg af 14. juli 2009. I notatet redegøres for regeringens besvarelse af Kommissionens åbningsskrivelse fra maj 2009, som blandt andet vedrører gensidig anerkendelse af recepter.

Øvrige bestemmelser om samarbejde mellem de nationale sundhedssystemer
Artiklerne 13, 15, 16 og 17 i Kommissionens oprindelige forslag omhandler samarbejde mellem de nationale sundhedsvæsener vedrørende etablering af europæiske referencenetværk, samarbejde om e-sundhed og samarbejde om forvaltning af ny sundhedsteknologi. Forslaget omfatter endvidere en artikel 18 om dataindsamling til statistik og overvågningsformål.

Der var med det oprindelige forslag lagt op til et forholdsvis forpligtende samarbejde på de nævnte områder og herunder til udbredt anvendelse af komitologi. Under forhandlingerne i Rådet har der imidlertid ikke været opbakning til Kommissionens forslag, idet de fleste medlemsstater har ønsket en højere grad af frivillighed i samarbejdet. Rådets Juridiske Tjeneste har i den forbindelse vurderet, at Fællesskabet ikke har kompetence til at vedtage visse dele af samarbejdskapitlet i den form, det havde i det tidligere tjekkiske formandskabs kompromisforslag fra marts 2009.

På den baggrund er kapitel IV tilpasset, så der bliver tale om et frivilligt samarbejde, og så det sikres, at bestemmelserne ligger inden for rammerne af Fællesskabets beføjelser i henhold til Traktaten. Artikel 18 om dataindsamling og statistik er udgået af forslaget

9. Eksempler på hvad direktivforslaget vil betyde for patienter med en "almindelig lidelse"

Hospitalsbehandling
Danske patienters har – udover behandling på offentlige sygehuse – adgang til vederlagsfri behandling efter det udvidede frie sygehusvalg (1 månedsreglen), reglerne om maksimale ventetider for livstruende sygdomme og reglerne om højt specialiseret behandling i udlandet m.v. Reglerne indebærer, at det kun er undtagelsesvist, at patienterne ikke kan få rettidig behandling her i landet.

Hertil kommer, at Danmark har implementeret de EU-regler om patienters grænseoverskridende sygehusrettigheder, som følger af EF-Domstolens retspraksis, i bekendtgørelse nr. 594 af 11. juni 2009 om ret til sygehusbehandling m.v., jf. vejledning om dækning af sygehusbehandling i andre EU- og EØS-lande. Disse regler indebærer, at patienter kan søge deres bopælsregion om forhåndsgodkendelse af refusion af udgifter til sygehusbehandling i et andet EU-land. Og regionen skal give en sådan forhåndstilladelse, hvis den ikke kan tilbyde patienten rettidig behandling, dvs. behandling indenfor en lægefagligt forsvarlig tidsfrist.

Implementeringen af direktivforslaget i den form, som det forligger nu (kompromisforslaget af 31. juli 2009) vil ikke give patienterne rettigheder med hensyn til refusion af udgifter til *sygehus*behandling i et andet EU-land, som ikke allerede følger af nævnte lovgivning. Et tænkt eksempel på hvordan reglerne kunne virke, kunne være følgende:

En patient er henvist af en læge til et sygehus i bopælsregionen med henblik på at få en ny hofte. Sygehuset meddeler patienten, at ventetiden på operation er 1 år, og at der pt. ikke er nogen andre offentlige sygehuse – eller private sygehuse mv. som har aftale med Danske Regioner efter den udvidede fritvalgsordning – som kan modtage patienten tidligere. Patienten får tiltagende smerter og tilstanden forværres løbende. Patienten søger derefter bopælsregionen om forhåndsgodkendelse af udgifter til operation på et privathospital i Tyskland og fremlægger et behandlingstilbud fra det tyske hospital. Bopælsregionen foretager en vurdering af, om den kan rykke patienten frem på regionens venteliste, og da det ikke kan lade sig gøre, om det er fagligt forsvarligt at lade patienten vente 1 år på en operation. Regionen når ud fra en samlet vurdering af patientens tilstand, herunder af smerter og udviklingen af sygdommen mv. frem til, at regionen ikke kan tilbyde patienten behandling inden for en lægefagligt forsvarlig tidsfrist. Regionen giver derfor patienten en forhåndsgodkendelse af refusion af patientens udgifter til operation på det pågældende tyske privathospital og oplyser refusionens størrelse, som svarer til DRG-taksten. Patienten sender efter endt behandling dokumentation i form af den betalte hospitalsregning til bopælsregionen, der derefter udbetaler den forhåndsgodkendte refusion, som er 70.447 kr. (DRG taksten i 2009 for en ny hofte).

Ikke-hospitalsbehandling
Hvis gruppe 1-sikrede fremover kan få tilskud til almen lægebehandling i udlandet vil det f.eks. betyde, at en dansk gruppe 1-sikret, der opsøger en almen læge i

Malmø for at få fjernet en fodvorte, selv skal betale udgifterne for behandlingen hos den svenske læge. Efterfølgende kan den sikrede søge regionen om tilskud til den modtagne ydelse, svarende til et konsultationshonorar på kr. 128,76 (okt. 2009 sats).

En tysk kvinde, der er gruppe 1-sikret i Danmark, men som vælger at opsøge en almen læge i Tyskland for vejledning om sterilisation, kan efter betaling af den tyske læge søge regionen om tilskud til den modtagne ydelse, svarende til et konsultationshonorar på kr. 128,76 og tillægsydelse for vejledning om sterilisation på kr. 132,37 (okt. 2009 sats).

10. Sammenfattende om status for forhandlingerne
En vedtagelse af direktivet i den foreliggende form vil kun i begrænset omfang medføre ændringer i forhold til danske patienters eksisterende muligheder for at søge behandling i andre medlemsstater.

Dog er det regeringens forventning, at forhandlingerne vil resultere i en løsning, som indebærer, at danske borgere fremover vil kunne få tilskud til medicin købt på et apotek i et andet EU-land og til medicin købt i Danmark på baggrund af en udenlandsk recept.

Herudover kan det ikke udelukkes, at der med direktivet vil blive åbnet op for, at danske gruppe 1-sikrede fremover vil kunne få tilskud til almen lægehjælp i andre medlemsstater og at en henvisning fra den udenlandske læge kan anvendes i Danmark såvel som i udlandet. Det bemærkes i den forbindelse, at det allerede i dag efter de danske regler herom er muligt for gruppe 1-sikrede at få tilskud til speciallægebehandling i andre medlemsstater, men at dette i dag forudsætter henvisning fra patientens egen læge i Danmark.

11. Regeringens holdning til formandskabets kompromisforslag
Regeringen er grundlæggende positivt indstillet over for, at der med direktivforslaget sikres større retlig klarhed og sikkerhed vedrørende patienternes muligheder for at søge behandling i andre EU-lande.

Kommissionens oprindelige forslag rejste imidlertid en række væsentlige spørgsmål i forhold til de mulige konsekvenser for indretning, styring og planlægning af de nationale sundhedssystemer samt i forhold til de mulige finansielle konsekvenser.

Under forhandlingerne i Rådet er forslaget ændret på en række væsentlige punkter og drøftelserne går nu i retning af et kompromis, som regeringen forventer at kunne tilslutte sig.

Med forbehold for at der kan være behov for tekniske justeringer i teksten, kan regeringen således samlet set acceptere det foreliggende svenske kompromisforslag. Kompromisforslaget imødekommer ikke de danske synspunkter vedrørende medicintilskud og spørgsmålet om almen lægehjælp til gruppe 1-sikrede. Regeringen finder derfor, at Danmark under forhandlingerne bør fortsætte bestræbelserne på at overbevise de andre medlemslande, men at disse to udestående spørgsmål ikke i sidste ende skal være afgørende for Danmarks stillingtagen til et resultat, som samlet set er tilfredsstillende.

Endvidere finder regeringen, at spørgsmålet om patienters udlæg og eventuel indførelse af en ordning med direkte afregning af udgifter er et nationalt anliggende, som ikke bør reguleres i EU-regi. Med det foreliggende forslag er der imidlertid alene tale om at understrege medlemsstaternes mulighed for på frivillig basis at indføre sådanne ordninger, hvilket regeringen ikke har indvendinger imod.

COUNCIL OF
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Brussels, 31 July 2009

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NOTE

from :	General Secretariat of the Council
to :	Working Party on Public Health
No prev. doc.	10231/09 SAN 151 SOC 365 MI 222 CODEC 759
No. Cion prop. :	11307/08 SAN 136 SOC 389 MI 234 CODEC 904
Subject :	**Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare** - *Presidency compromise proposal*

Delegations will find in the Annex the Presidency's compromise proposal concerning the above draft directive.

Please note that changes with respect to document 10231/09 are marked by ~~strikethrough~~ for deletions and **bold underlined** for additions.

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the application of patients' rights in cross-border healthcare

(2) **For the majority of the provisions in this Directive, Articles 47(2), 55 and 95 of the Treaty is the appropriate legal base since the provisions have the aim of improving the functioning of the internal market and the free movement of goods, services and persons.** Given that that the conditions for recourse to Article 95 of the Treaty as a legal basis are fulfilled, the Community legislature shall rely on this legal basis even when public health protection is a decisive factor in the choices made; in this respect Article 95(3) of the Treaty explicitly requires that, in achieving harmonisation, a high level of protection of human health should be guaranteed taking account in particular of any new development based on scientific facts. **However, Articles 13 and 15 of this Directive have the aim of providing incentive measures for cooperation between the Member States in the area of healthcare. For these Articles, Article 152(4)(c) of the Treaty is therefore the appropriate legal base.**

(9) This Directive on the application of patients' rights in cross-border healthcare applies to individual patients who decide to seek healthcare in a Member State other than the Member State of affiliation. As confirmed by the Court of Justice, neither its special nature nor the way in which it is organised or financed removes healthcare from the ambit of the fundamental principle of freedom to provide services. **However, if there are legitimate concerns over the safety and quality of care provided by a healthcare provider outside of the social security system in the Member State of treatment, this Directive provides the Member State of affiliation with the possibility of excluding this healthcare provider from the scope of the relevant provisions.**

~~This Directive shall apply to the provision of healthcare regardless of whether it is provided by healthcare provider who is or is not in a contractual relation to the social security system. However, if there is, in an individual case, a serious risk to the public policy, public security or public health caused by the fact, that the concrete health provider is not bound by any contract to the social security system, so that the quality or safety of healthcare is threatened, the Member States may take measures in accordance with Articles 46 and 55 of the EC Treaty.~~

(9a) In this Directive, healthcare means all health services and goods provided or prescribed by health professionals to patients to assess, maintain or restore their state of health. However, it is clear that the obligation to reimburse costs of cross-border healthcare shall be limited to healthcare for which the insured person is entitled to according to the legislation of his/her Member State of affiliation.

(9b) **This** ~~As regards long-term care, the~~ Directive does not apply to ~~the social care part of long-term care and to the~~ services whose primary purpose is to support people in need of assistance in carrying out routine, everyday tasks. More specifically this refers to those long-term care services deemed necessary in order to enable the person in need of care to live as full and self-determined life as possible. ~~These include, in particular, basic hands-on care services (like bathing, dressing, eating, getting in and out of bed or chair, moving around and using the bathroom), domestic work/home help (like housework, meals, shopping, transport and social activities).~~ Thus, this Directive should not apply, for example, to long-term care services provided in residential homes or housing **("nursing homes")**, ~~or assistance provided to elderly people or children to long-term care services provided in residential facilities ("nursing homes")~~ by home care services or in assisted living facilities.

(9c) The access to and allocation of organs for the purpose of organ transplants fall outside the scope of this Directive. However, the medical treatment of transplanting organs fall within the scope of this Directive.

(10) For the purpose of this Directive, ~~the concept of~~ "cross-border healthcare" means:

- a situation in which the patient physically receives healthcare provided in a Member State other than that where **he or she is an** ~~the~~ insured person ~~has social security affiliation; this is what is referred to as "patients mobility";~~

- provision of healthcare services, through use of Information and Communication Technologies (ICT), in situations where the health professional (or **several** ~~more~~ health professionals) and the patient are not in the same **Member State.** ~~location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients; this is what is referred to as "telemedicine";~~

- the purchase of goods connected with healthcare, such as medicinal products and medical devices, in a Member State other than that where the insured person has social security affiliation or in **the** case when the medicinal product or medical device is purchased in another Member State than that where the prescription was issued.

(10a) This Directive does not give any person an entitlement to enter, stay or reside in a Member State in order to receive healthcare in that State. In case that the stay of a person on the territory of a Member State is not in accordance with the legislation of that Member State concerning the right to enter or stay on its territory, such person is not regarded as an insured person according to the definition ~~of the insured person set~~ in this Directive.

(12) In order to enable patients to make an informed choice when they seek to receive healthcare in another Member State, the Member State of treatment shall ensure that patients **from other Member States** receive on request the relevant information on health and quality standards enforced on its territory as well as on ~~the characteristics of healthcare provided by a specific~~ healthcare provider**s subject to these standards.**

(12aa) In order to further enable patients to make an informed choice, healthcare providers should provide patients on request with information on several aspects of the healthcare services they offer. To the extent that healthcare providers already provide patients resident in the Member State of treatment with relevant information on these subjects, this Directive does not oblige healthcare providers to provide more extensive information to patients from other Member States. Furthermore, the Member State of treatment may oblige other actors than the healthcare providers, such as insurance providers or public authorities, to provide this information if this is more suitable with regard to the organisation of its healthcare system.

(12a) Members States **should** ~~have to~~ ensure that all patients are treated equitably on the basis of their healthcare need rather than their Member State of social security affiliation. In doing so, Member States **should** ~~must~~ respect the principles of free movement of persons within the internal market, non-discrimination inter alia with regard to nationality and necessity and proportionality of any restrictions on free movement. However, nothing in this Directive requires healthcare providers to accept for planned treatment or to prioritise patients from other Member States to the detriment of other patients, such as through increasing waiting time for treatment. Inflows of patients may create a demand exceeding the capacities existing in a Member State for a given healthcare. In such exceptional cases, the Member State should retain the possibility to remedy the situation on the grounds of public health, in accordance with Articles 46 and 55 of the EC Treaty. However this limitation is without prejudice to the Member States obligations under Regulation No (EC) 883/2004.

(12b) In the light of the case-law of the Court of Justice (judgment of 11 March 2004, Commission v France, C-496/01), in the absence of harmonisation measures, Community law does not preclude a Member State from imposing, in context of an authorisation scheme, its level of public health protection on healthcare providers established in another Member State which wish to offer services to patients insured in the first Member State. However, the conditions to be satisfied in order to obtain such authorisation may not duplicate the equivalent statutory conditions, which have already been satisfied in the Member State of establishment.

(25) This Directive does not aim to create entitlement for reimbursement of cost of healthcare provided in another Member State, if such healthcare is not among the benefits provided for by the legislation of the Member State of affiliation of the insured person. Equally, this Directive does not prevent the Member States from extending their benefits in kind scheme to healthcare provided in another Member State according to its provisions. This Directive recognises that Member States are free to organise their own healthcare and social security systems in such a way as to determine entitlement for treatment at a regional or local level.

(26a) Member States should be free to set up voluntary systems or prior notification whereby patients can get written confirmation in advance whether they will be reimbursed after receiving a certain treatment, and if applicable with what amount, and to provide for the assumption of costs through other means than reimbursement ex-post, such as through advance payment or direct payment between institutions, as long as these arrangements comply with Community law. Likewise, Member States should be free to reimburse patients with a higher amount than the level of costs that would have been assumed had the healthcare been provided on its territory.

(27) This Directive provides also for the right for a patient to receive any medicinal product authorised for marketing in the Member State of treatment, even if the medicinal product is not authorised for marketing in the Member State of affiliation, as it is an indispensable part of obtaining effective treatment in another Member State. Nothing obliges a Member State of affiliation to reimburse an insured person for a medicinal product prescribed in the Member State of treatment, which is not among the benefits provided to that insured person by the social security system in the Member State of affiliation.

(28) Member States may maintain general conditions, criteria for eligibility and regulatory and administrative formalities for receipt of healthcare and reimbursement of healthcare costs, such as the requirement to consult a general practitioner before consulting a specialist or before receiving hospital care, also in relation to patients seeking healthcare in another Member State provided that such conditions are necessary, proportionate to the aim and are not discretionary and discriminatory. It is thus appropriate to require that these general conditions and formalities are being applied in an objective, transparent and non-discriminatory way and are known in advance, based primarily on medical considerations and that they do not impose any additional burden on patients seeking healthcare in another Member State in comparison with patients being treated in their Member State of affiliation, and that decisions are made as quickly as possible. **This is without prejudice to the rights of the Member States to provide for criteria or conditions of prior authorisation in the case of patients seeking healthcare in their Member State of affiliation. Since conditions, criteria and formalities relating to entitlements to healthcare, such as determining the cost-effectiveness of a specific treatment for a specific patient, is a matter for the Member State of affiliation, such conditions, criteria and formalities cannot be required in the Member State of treatment as well as this would constitute an obstacle to the free movement of persons, goods and services. However, the Member State of treatment may impose conditions, criteria and formalities relating to clinical circumstances, such as assessing patient safety risks in performing a specific procedure on a specific patient**. ~~If the administrative formalities for assumption of costs are required in the Member State of treatment as well as in the Member State of affiliation, under the principle of equal treatment, such double requirement would be an obstacle to free movement.~~

Furthermore, these conditions, criteria and formalities could include a procedure that ensures that a person seeking healthcare in another Member State has been provided with all technical, professional and medical support required for making an informed choice of healthcare provider, if this procedure is neither discriminatory nor an obstacle to the free movement of persons, services or goods. ~~This is without prejudice to the rights of the Member States to provide for criteria or conditions of prior authorisation in the case of patients seeking healthcare in their Member State of affiliation.~~

(29) In the light of the case-law of the Court of Justice, making the assumption by the national social security system of costs of healthcare provided in another Member State subject to prior authorisation is a restriction to free movement of services. Therefore, as a general rule, the Member State of affiliation should not make the assumption of the costs of healthcare provided in another Member State subject to prior authorisation, where the costs of that care, if it had been provided in its territory, would have been paid for by its social security system.

(30) deleted

(31) According to the constant case-law of the Court of Justice, Member States may make the assumption of costs by the national system of hospital care provided in another Member State subject to prior authorisation. The Court has judged that this requirement is both necessary and reasonable, since the number of hospitals, their geographical distribution, the way in which they are organised and the facilities with which they are provided, and even the nature of the medical services which they are able to offer, are all matters for which planning, generally designed to satisfy various needs, must be possible. The Court has found that for one thing, such planning seeks to ensure that there is sufficient and permanent access to a balanced range of high-quality hospital treatment in the Member State concerned. For another thing, it assists in meeting a desire to control costs and to prevent, as far as possible, any wastage of financial, technical and human resources. According to the Court, such wastage would be all the more damaging because it is generally recognised that the hospital care sector generates considerable costs and must satisfy increasing needs, while the financial resources which may be made available for healthcare are not unlimited, whatever the mode of funding applied.

(31a) The same reasoning applies to healthcare not provided in a hospital but subjected to similar planning needs in the Member State of treatment. This may be healthcare which requires planning because it involves use of highly specialised and cost-intensive medical infrastructure or medical equipment. With regard to the progress of technology, the development of new methods of treatment and the different policies of Member States regarding the roles of hospitals in their healthcare systems, whether this kind of healthcare is delivered within hospital or ambulatory care facilities is not the decisive factor for deciding whether it requires planning or not.

(31b) Given that the Member States are responsible for laying down rules as far as the management, the requirements, the quality and safety standards **and** ~~in~~ the organisation and delivery of healthcare and that the planning necessities differ from one Member State to another, it is therefore for the Member States to decide whether there is a need to introduce the system of prior authorisation, and if so, to identify the healthcare requiring prior authorisation in the context of their system, in accordance with the criteria defined by this Directive and in the light of the case law of the Court of Justice. The information concerning this care shall be made publicly available for all the patients.

(31c) The criteria attached to the grant of prior authorisation **should** ~~must~~ be justified in the light of the overriding reasons in the general interest capable of justifying obstacles to the free movement of healthcare. The Court of Justice has identified several potential considerations: the risk of seriously undermining the financial balance of a social security system, the objective of maintaining on grounds of public health a balanced medical and hospital service open to all or the objective of maintaining treatment capacity or medical competence on national territory, essential for the public health, and even the survival of the population. Conversely, the refusal to grant prior authorisation may not be based solely on the ground that there are waiting lists on national territory intended to enable the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out an objective medical assessment of the patient's medical condition, the history and probable course of his illness, the degree of pain he/she is in and/ or the nature of his disability at the time when the request for authorisation was made or renewed.

(31d) **According to the constant case-law of the Court of Justice, the criteria for granting or refusing prior authorisation shall be limited to what is necessary and proportionate in the light of these overriding reasons in the general interest. It should be noted that the impact on national health systems caused by patient mobility might vary between Member States or between regions within a Member State, depending on factors such as geographical location, language barriers, location of hospitals in border regions or the size of the population and/or healthcare budget. Therefore it should be for every Member State to set up such criteria for refusing prior authorisation that are necessary and proportionate in that specific context, also taking into account which healthcare that fall within the scope of the prior authorisation system since certain treatments of a highly specialised nature will be more easily affected even by a limited patient outflow than others. Therefore, Member States might set up different criteria for different regions or other relevant administrative levels for the organisation of healthcare, or indeed for different treatments, as long as the system is transparent and easily accessible and the criteria is made public in advance.**

(33) Procedures regarding cross-border healthcare established by the Member States should give patients guarantees of objectivity, non discrimination and transparency, in such a way as to ensure that decisions by national authorities are made in a timely manner and with due care and regard for both those overall principles and the individual circumstances of each case. **This applies also to the actual reimbursement of costs of healthcare incurred in another Member State after the patient's return**. ~~It is appropriate that patients should normally have a decision regarding the cross-border healthcare within fifteen calendar days. However, that period should be shorter where warranted by the urgency of the treatment in question. In any event, recognition procedures and rules on the provision of services as provided for by Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications should not be affected by these general rules.~~

(34) Appropriate information on all essential aspects of cross-border healthcare is necessary in order to enable patients to exercise their rights on cross-border healthcare in practice. For cross-border healthcare one of the mechanisms for providing such information is to establish national contact points within each Member State. Information that have to be provided compulsorily to patients are specified, however the national contact points may provide more information voluntarily and also with the support of the European Commission. Information shall be provided for by national contact points to patients in any of the official languages of the Member State in which the contact points are situated. Information may, but does not have to, be provided also in languages other than in the official languages of the Member State in which the national contact points are situated.

(39) Where medicinal products are authorised within the patient's Member State in accordance with Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[1] and have been prescribed in another Member State for an individual named patient, it should be in principle possible for such prescriptions to be medically recognised and used in the patient's own Member State. The removal of regulatory and administrative barriers to such recognition is without prejudice to the need for appropriate agreement of the patients' treating physician or pharmacist in every individual case, if this is warranted by protection of human health and is necessary and proportionate to that objective. **The recognition of prescriptions from other Member States shall not affect national rules governing dispensing, including any professional or ethical duty that would require the pharmacist to refuse to dispense the prescription**. Such medical recognition should also be without prejudice to the decision of the Member State of affiliation regarding the inclusion of such medicinal products within the benefits covered by the social security system of affiliation. **It should further be noted that the reimbursement of medicinal products is not affected by the rules on mutual recognition of prescriptions, but covered by the general rules on reimbursement of cross-border healthcare in chapter III of this Directive.** The implementation of the principle of recognition will be facilitated by the adoption of measures necessary for safeguarding the safety of a patient, and avoiding the misuse or confusion of medicinal products.

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1 OJ L 311, 28.11.2001, p. 67. Directive as last amended by Regulation (EC) No 1901/2006 of the European Parliament and of the Council (OJ L 378, 27.12.2006, p. 1).

(45a) In accordance with point 34 of the Interinstitutional Agreement on better law-making, Member States are encouraged to draw up, for themselves and in the interests of the Community, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public.

CHAPTER I

GENERAL PROVISIONS

Article 1

Aim

This Directive provides for rules for the access to safe and high-quality cross-border healthcare and establishes cooperation mechanisms on healthcare between Member States, in full respect of national competencies in organising and delivering healthcare.

Article 2

Scope

This Directive shall apply to the provision of healthcare to patients, regardless of how it is organised, delivered and financed.

This Directive shall not apply to services in the field of long-term care whose purpose is to support people in need of assistance in carrying out routine, everyday tasks.

This Directive shall not apply to allocation and access to organs for the purpose of organ transplants.

Article 3

Relationship with other Community provisions

This Directive shall apply without prejudice to:

(a) Directive 2005/36/EC on the recognition of professional qualifications;

(b) Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market;

(c) Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data and Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector;

(d) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;

(da) Directive 2001/83/EC on the Community code relating to medicinal products for human use;

(e) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use;

(ea) Directive 89/105 Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems;

(f) Directive 96/71/EC of the European Parliament and of the Council of 16 December 1996 concerning the posting of workers in the framework of the provision of services;

(g) Directive 2000/43/EC of the Council of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin;

(h) Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems and its implementing Regulation;

(i) Regulation (EC) No 1338/2008 of the European Parliament and of the Council on Community statistics on public health and health and safety at work;

(j) Regulation (EC) 1082/2006 of 5 July 2006 on a European Grouping of territorial cooperation (EGTC);

(k) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC;

(l) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells;

(m) "Council Regulation (EC) No 859/2003 of 14 May 2003 extending the provisions of Regulation (EEC) No 1408/71 and Regulation (EEC) No 574/72 to nationals of third countries who are not already covered by those provisions solely on the ground of their nationality".

Article 4

Definitions

For the purposes of this Directive, the following definitions shall apply:

(a) "healthcare" means health services **provided** and goods, in particular medicinal products and medical devices, ~~provided or~~ prescribed **or dispensed** by health professionals to patients to assess, maintain or restore their state of health;

(b) "Member State of affiliation" means the Member State where the patient is an insured person; ~~if, due to the application of Article 20(4) or Article 27(5) of the Regulation (EC) No 883/2004, the institution of the place of residence is considered to be the competent institution, the state of residence shall be considered as a Member State of affiliation;~~

Where, due to the application of Regulation (EC) No 883/2004, the health insurance body in the Member State of residence of the patient is responsible for the provision of benefits in accordance with the legislation of that state, then that Member State is regarded as the Member State of affiliation for the purposes of this Directive;

(c) "Member State of treatment" means the Member State on whose territory healthcare is actually provided to the patient;

(d) "cross-border healthcare" means healthcare provided or prescribed in a Member State other than the Member State of affiliation;

(e) "health professional" means a doctor of medicine or a nurse responsible for general care or a dental practitioner or a midwife or a pharmacist within the meaning of Directive 2005/36/EC or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC or a person considered to be a health professional according to the legislation of the Member State of treatment;

(f) "healthcare provider" means any natural or legal person or any other entity legally providing healthcare on the territory of a Member State;

(g) "patient" means any natural person who seeks to receive or receives healthcare in a Member State;

(h) "insured person" means a person who is eligible for the assumption of costs of healthcare by a ~~statutory~~ social security system according to the legislation of **a** ~~the~~ Member State ~~of affiliation~~;

(i) "medicinal product" means a medicinal product as defined by Directive 2001/83/EC;

(j) "medical device" means a medical device as defined by Council Directive 93/42/EEC of 14 June 1993 concerning medical devices or by Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices or by Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices;

(k) "prescription" means a prescription for a medicinal product or a prescription for a medical device issued by a health professional legally entitled to do so in the Member State in which the prescription is issued;

(l) "health technology" means a medicinal product or a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare.

(m) "medical records" means all the documents containing data, assessments and information of any kind on a patient's situation and clinical development throughout the care process.

(n) "social security system" means the statutory social security system or the statutory healthcare system of a Member State.

(o) "planned cross-border healthcare" means such cross-border healthcare that falls outside the scope of Article 19 in Regulation (EC) No 883/2004.

CHAPTER II

RESPONSIBILITIES OF MEMBER STATES WITH REGARDS TO CROSS-BORDER HEALTH CARE

Article 5

Responsibilities of the Member State of treatment

1. Cross-border healthcare shall be provided in accordance with the legislation of the Member State of treatment and according to standards and guidelines on quality and safety defined by that Member State.

2. The Member State of treatment shall ensure that:

   (a) patients receive upon request relevant information on standards and guidelines referred to in paragraph 1, including provisions on supervision and assessment **of healthcare providers, and information on healthcare providers that are subject to these standards and guidelines;**

   (b) healthcare providers provide individual patients with relevant information on availability, prices and quality and safety of the healthcare they provide in the Member State of treatment, as well as on the healthcare providers' authorisation **or registration status**, their insurance cover or other means of personal or collective protection with regard to professional liability. ~~This information shall be provided to the same extent as to the nationals of the Member State of treatment;~~

   (ba) prices charged for healthcare to patients from other Member States are calculated according to objective, non-discriminatory criteria known in advance, without affecting the prerogative of private providers to set prices freely, as long as they do not discriminate against patients from other Member States;

   (c) there are systems in place of making complaints and mechanisms in place for patients to seek remedies in accordance with the legislation of the Member State of treatment if they suffer harm arising from the healthcare they receive;

(d) systems of professional liability insurance or a guarantee or similar arrangement, which are equivalent or essentially comparable as regards their purpose and which are appropriate to the nature and the extent of the risk, are in place for treatment provided on its territory;

(e) ~~patients have access to at least a copy of their medical records, with regards to the healthcare received in the Member State of treatment and in compliance with its legislation, and that~~ the fundamental right to privacy with respect to the processing of personal data is protected in conformity with national measures implementing Community provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC;

(f) patients who have received treatment are entitled to a written or electronic medical record of such treatment, and access to this record or a copy thereof in conformity with and subject to national measures implementing Community provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.

3. Patients from other Member States shall enjoy equal treatment with **patients affiliated to the social security system of the** ~~nationals of the~~ Member State of treatment.

This shall be without prejudice to the possibility for the Member State of treatment, where it is justified by overriding reasons of general interest, ~~such as management of national or multi national waiting lists in the context of organ shortage~~, to adopt measures **regarding the access to treatment** aimed at fulfilling its fundamental responsibility to ensure sufficient and permanent access to healthcare on its territory.

Such measures shall be limited to what is necessary and proportionate and shall not constitute a means of arbitrary discrimination.

Article 6

Responsibilities of the Member State of affiliation

1. The Member State of affiliation shall ensure that cost of cross-border healthcare is reimbursed in accordance with Chapter III.

2. The Member State of affiliation shall ensure that there are mechanisms in place to provide patients on request with information on their rights and entitlements in this Member State related to receiving cross-border healthcare, in particular as regards procedures for accessing and determining those entitlements, conditions for reimbursement of costs and systems of appeal and redress if the patient considers that his/her rights have not been respected.

3. The Member State of affiliation shall ensure that patients **that seek to receive or receives cross-border healthcare** have access to ~~at least a copy of~~ their medical records, **or a copy thereof**, ~~with regards to the healthcare received in the Member State of affiliation and in compliance with its legislation, when they seek to receive or receive cross-border healthcare, and that the fundamental right to privacy with respect to the processing of personal data is protected~~ in conformity with **and subject to** national measures implementing Community provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC

Article 7

National contact points for cross-border healthcare

1. Each Member State shall designate one or more national contact points for cross-border healthcare and communicate their names and contact details to the Commission.

2. National contact points shall cooperate with each other and with the Commission. National contact point(s) shall provide patients on request with contact details of national contact point(s) in other Member States.

3. National contact point(s) in the Member State of treatment shall provide patients with information concerning healthcare providers, **including on request information on a specific providers' right to provide services or any restrictions on its practice**, information on existing quality and safety standards and guidelines, patients' rights, procedures for complaints and for seeking remedies, according to legislation of the Member State.

4. National contact point(s) in the Member State of affiliation shall provide patients with information referred to in Article 6(2).

5. The information shall be easily accessible, including by electronic means.

CHAPTER III

REIMBURSEMENTOF COSTS OF PLANNED CROSS-BORDER HEALTHCARE

Article 8

General principles for reimbursement of costs

1. Subject to the provisions of Articles 9 and 10, the Member State of affiliation shall ensure reimbursement of costs incurred by an insured person who received planned cross-border healthcare, if the healthcare in question is among the benefits to which the insured person is entitled in the Member State of affiliation.

2. It is for the Member State of affiliation to determine, whether at a local, regional or national level healthcare for which an insured person is entitled to assumption of costs and the level of assumption of those costs, regardless of where it is provided.

3. The costs of **planned** cross-border healthcare shall be reimbursed by the Member State of affiliation up to the level of costs that would have been assumed by the Member State of affiliation, had this healthcare been provided in its territory without exceeding the actual costs of healthcare received.

4. For the purposes of the provisions of paragraph 3, Member States shall have a mechanism for calculation of costs of **planned** cross-border healthcare that are to be reimbursed to the insured person by the statutory social security system. This mechanism shall be based on objective, non-discriminatory criteria known in advance. **The mechanism shall be applied at the relevant administrative level in cases where the Member State of affiliation has a decentralised healthcare system.**

5. The Member State of affiliation may impose on an insured person seeking reimbursement of costs of **planned** cross-border healthcare the same conditions, criteria of eligibility and regulatory and administrative formalities, whether set at a local, regional or national level, ~~including any assessment by a health professional or healthcare administrator, providing services for the statutory social security system of the Member State of affiliation~~ as it would impose if this healthcare was provided in its territory, ~~in so far as they are neither discriminatory nor an obstacle to free movement of persons, services and goods.~~ **This may include an assessment by a health professional or healthcare administrator providing services for the social security system of the Member State of affiliation if this is necessary for determining the individual patient's entitlement to healthcare. However, no conditions, criteria of eligibility and regulatory and administrative formalities imposed according to this paragraph may be discriminatory or constitute an unjustified obstacle to the free movement of persons, services or goods.**

~~6. Member States shall ensure that requests regarding of cross-border healthcare are dealt with objectively and impartially within reasonable maximum time limits set out and made publicly available in advance by the Member States.~~

~~7. Member States shall ensure that any administrative decisions regarding of cross-border healthcare are subject to administrative review and also capable of being challenged in judicial proceedings, which include provision for interim measures.~~

6. ~~8.~~ The Member State of affiliation shall not make the reimbursement of costs of **planned** cross-border healthcare subject to prior authorisation with the exception of Article 9.

7. **For the purposes of reimbursing cross-border healthcare according to this Article, the Member State of affiliation may exclude healthcare providers that are not, by contract, accreditation or otherwise, part of the social security system of the Member State of treatment if:**

a) **the provider is not subject to at least the same or equivalent standards and guidelines on quality and safety, including provisions on supervision, as providers that are part of the social security system in the Member State of treatment, and**

b) **the decision to exclude a healthcare provider according to this paragraph is based on legitimate concerns over the quality and safety of the healthcare provided by the healthcare providers in question and does not constitute a means of arbitrary discrimination.**

Article 9

Healthcare that may be subject to prior authorisation

1. **The Member State of affiliation may make the reimbursement of costs of planned cross-border healthcare subject to prior authorisation, in accordance with the provisions of this Article and Article 10.**

2. ~~1. For the purposes of reimbursement of costs of cross-border healthcare in accordance with this Directive, h~~ Healthcare that may be subject to prior authorisation shall be limited to healthcare ~~as defined by the legislation of the Member State of affiliation~~ which **is made subject to planning in so far as it**:

(a) ~~is made subject to planning in so far as it~~ involves overnight accommodation of the patient in question for at least one night or

(b) requires use of highly specialised and cost-intensive medical infrastructure or medical equipment or

(c) involves treatments presenting a particular risk for the patient or the population.

~~2. The Member State of affiliation may make the reimbursement of costs of cross-border healthcare as defined in paragraph 1 subject to prior authorisation by introducing a system of prior authorisation.~~

3. The system of prior authorisation shall be limited to what is necessary and proportionate and shall not constitute a means of arbitrary discrimination.

4. **The criteria for refusing prior authorisation to patients shall be limited to what is necessary and proportionate with regard to overriding reasons in the general interest.**

5. The Member State of affiliation may refuse to grant a prior authorisation for reasons including, but not limited to the following:

(a) the patient is not entitled to the treatment in question, in accordance with Article 8 of this Directive;

(b) if this healthcare can be provided on its territory within a time-limit which is medically justifiable, taking into account the current state of health and the probable course of the illness of the person concerned;

(c) if the patient according to a clinical evaluation with reasonable certainty will be exposed to a safety hazard that cannot be considered to be normal, taking into account the potential benefit for the patient of the sought cross-border healthcare;

(d) if the general public with reasonable certainty will be exposed to a substantial safety hazard as a result of the cross-border healthcare in question;

6. ~~4.~~ The Member State of affiliation shall make publicly available which **cross-border** healthcare is subject to prior authorisation as well as all relevant information on the system of prior authorisation.

Article 10

Procedures regarding crossborder healthcare ~~requests for granting prior authorisation~~

1. The Member State of affiliation shall ensure that administrative procedures regarding the use of crossborder healthcare and reimbursement of costs of healthcare incurred in another Member State are based on objective, non-discriminatory criteria which are made publicly available in advance, and which are necessary and proportionate to the objective to be achieved.

2. **Any such procedural systems shall be easily accessible and capable of ensuring that requests are dealt with objectively and impartially within reasonable time limits set out and made public in advance by the Member States. Urgency and individual circumstances shall be taken into account when dealing with such requests.** ~~When dealing with a request for prior authorisation by an insured person, the Member State of affiliation shall take into account urgency and all the individual circumstances~~

3. The Member State of affiliation shall check whether the conditions of Regulation (EC) No 883/2004 are met. If that is the case, the prior authorisation shall be granted pursuant to that Regulation unless otherwise requested by the insured person.

4. Member States shall ensure that administrative decisions regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State are subject to administrative review and also capable of being challenged in judicial proceedings, which include provision for interrim measures.

~~4. In any event, the Member State of affiliation may refuse to grant a prior authorisation for reasons including, but not limited to the following:~~

~~(a) if this healthcare which is among the benefits provided for by the legislation of the Member State of affiliation and can be provided on its territory within a time-limit which is medically justifiable, taking into account of the current state of health and the probable course of the disease of the person concerned;~~

~~(b) if there is a clinical risk for the patient or the population if the patient receives cross-border healthcare.~~

CHAPTER IV

COOPERATION ON HEALTHCARE

Article 11

Mutual assistance and cooperation

1. Member States shall render such mutual assistance as is necessary for the implementation of this Directive**, including the exchange of information about standards and guidelines on quality and safety, including provisions on supervision, in order to facilitate the implementation of Article 8.7.**

2. Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level.

Article 12

Recognition of prescriptions issued in another Member State

1. **If a medicinal product or a medical device is authorised to be marketed on their territory,** Member States shall ensure that prescriptions issued ~~for an authorised medicinal product or a medical device~~ in another Member State for a named patient can be **executed** ~~used~~ in their territory in compliance with their national legislation in force and that any restrictions on recognition of individual prescriptions are prohibited unless they:

   (a) are limited to what is necessary and proportionate to safeguard human health and are non-discriminatory, or

   (b) are based on legitimate and justified doubts about the authenticity, content or comprehensibility of an individual prescription.

   The recognition of prescriptions shall not affect national rules governing dispensing, including generic substitution.

2. In order to facilitate implementation of paragraph 1, the Commission shall adopt:

(a) ~~before x months prior to the transposition date~~ measures enabling a health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by a health professional ~~qualified and~~ legally entitled to do so through developing a list of elements to be included in the prescriptions; ~~and~~

(b) **guidelines** supporting the Member States in developing the interoperability of ePrescriptions;

(c) ~~before x months prior to the transposition date~~ measures to **facilitate** ~~ensure~~ that medicinal products **or medical devices** prescribed in one Member State and dispensed in another are correctly identified**;** ~~and~~

(d) **measures to facilitate** that the information to patients concerning the product is comprehensible including specific measures for products not available in all Member States;

(e) if appropriate, measures to exclude specific categories of medicinal products **or medical devices** from the recognition of prescriptions provided for under this article where necessary in order to safeguard public health.

3. The measures **and guidelines** referred to in points (a), ~~and~~(b)**, (c) and (d)** of paragraph 2 shall be adopted in accordance with the regulatory procedure referred to in Article 16(2). The measures referred to in point **(e)** of paragraph 2, designed to amend non-essential elements of this Directive, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 16(3).

4. Paragraph 1 shall not apply to medicinal products subject to special medical prescription as provided for in Article 71(2) of Directive 2001/83/EC.

Article 13

European reference networks

1. The Commission shall support Member States **in** ~~by facilitating~~ the development of European reference networks **between healthcare providers and expertise in the Member States. The networks shall be based on voluntary participation by its members, which shall participate and contribute to the networks activities according to the legislation of the Member State where they are established.**

2. The **aim** ~~objective~~ of European reference networks shall be to help ~~to~~:

   (a) realise the potential of European cooperation regarding highly specialised healthcare for patients and for healthcare systems from innovations in medical science and health technologies;

   (b) facilitate access to diagnosis and to high quality and cost-effective healthcare for all patients with a medical condition requiring a particular concentration of expertise;

   (c) maximise cost-effective use of resources;

   (d) reinforce research, epidemiological surveillance like registries and provide training for health professionals;

   (e) facilitate mobility of expertise, virtually or physically and to develop, share and spread information, knowledge and best practice within and outside the networks;

   (f) Member States with an insufficient number of patients with a particular medical condition or lacking technology or expertise to provide highly specialised services.

~~3. Member States are encouraged to facilitate the development of the European reference networks:~~

~~(a) by identifying appropriate expertise throughout their national territory;~~

~~(b) by fostering the participation of expertise in the European reference networks.~~

3. For the purposes of paragraph 1, the Commission shall ~~adopt guidelines on~~:

(a) **develop and publish** criteria and conditions that the European reference networks should fulfil;

(b) **develop and publish** ~~the procedure for establishing, developing and~~ **criteria for** evaluating European reference networks ~~respecting the Member States competences and rules in regard of the authorisation or recognition of their own expertise~~

(c) facilitate the exchange of information and expertise in relation to the establishment of networks and their evaluation.

4. The criteria and conditions referred to in paragraph 3 (a) and (b). ~~These guidelines~~ shall be adopted in accordance with the procedure referred to in Article 16(2).

5. Measures adopted according to this Article shall not harmonize any laws or regulations of the Member States and shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.

Article 14

~~Cooperation on~~ eHealth ~~, including telemedicine~~

~~1.~~ Member States shall**, supported by the Commission,** aim at interoperability of information and communication technology systems, ~~through~~ in particular **through** specifying the necessary standards and terminologies for interoperability. ~~applicable whenever a Member State decides to introduce them.~~

~~2. In order to facilitate cooperation between Member States, the Commission shall, in accordance with the procedure referred to in Article 16(2) adopt guidelines concerning, in particular, interoperability of information and communication technology systems.~~

Article 15

Cooperation on health technology assessment

1. The **Community** ~~Commission~~ shall **support and** facilitate cooperation and the exchange of scientific information among Member States within a network connecting national authorities or bodies responsible for health technology assessment **designated by the Member States. The members of the network shall participate and contribute to the network's activities according to the legislation of the Member State where they are established.**

2. The objective of the **Community support** ~~network~~ referred to in paragraph 1 shall be:

   ~~(a)~~ to support Member State**s** in their cooperation between **the** national authorities or bodies **referred to in paragraph 1**

   ~~(b)~~ **and** to support Member States in the provision of objective, reliable, timely, transparent and transferable scientific information on the short- and long-term effectiveness of health technologies and enable an effective exchange of this information between **the** national authorities or bodies ~~without interfering in the Member States' competence to decide on the impact of the cost-benefit analysis for their own healthcare system.~~

3. In order to implement paragraph 2, the network on health technology assessment may receive Community aid. Aid may be given in order to:

(a) contribute to the financing of administrative and technical support;

(b) support Member States in developing and sharing methodologies for health technology assessment and relative effectiveness assessment;

(c) contribute to the financing of the provision of transferable scientific information to be used in national reporting and case studies commissioned by the network;

(d) facilitate cooperation between the network and other relevant institutions and bodies of the Community;

(e) facilitate the consultation of stakeholders.

~~3. Member States shall designate the authorities or bodies participating in the network referred to in paragraph 1 and communicate to the Commission names and contact details of those authorities or bodies.~~

4. Arrangements for granting the aid, the conditions to which it may be subject and its amount, shall be adopted ~~For the purposes of paragraph 1 the Commission shall~~ in accordance with the procedure referred to in Article 16(2)**.** ~~adopt guidelines concerning, in particular, the exchange of information within the network, including the nature and type of the information to be exchanged.~~ **Those authorities and bodies in the network designated as beneficiaries by the participating Member States shall be eligible for Community aid.**

5. The appropriations required for measures provided for in this Article shall be decided each year as part of the budgetary procedure.

6. Measures adopted according to this Article shall not harmonize any laws or regulations of the Member States and shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.

CHAPTER V

IMPLEMENTING AND FINAL PROVISIONS

Article 16

Committee

1. The Commission shall be assisted by a Committee, consisting of representatives of the Member States and chaired by the Commission representative.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 of that Decision. The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 3 months.

3. Where reference is made to this paragraph, Article 5a (1) to (4), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 17

Reports

1. The Commission shall within five years after the date referred to in Article 19, and subsequently every three years, draw up a report on the operation of this Directive and submit it to the European Parliament and to the Council.

2. The report shall in particular include information on patients' flows, financial dimensions of patients' mobility**, the implementation of Article 8(7)** and on the functioning of the European reference networks and national contact points. To this end, the Commission shall conduct assessment of the systems and practices put in place in the Member States, in the light of the requirements of this Directive and the other Community legislation relating to patients' mobility.

3. The Member States shall provide the Commission with all the necessary assistance and information for carrying out the assessment and preparing the reports.

Article 18

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by … [three years after its entry into force].

2. They shall forthwith communicate to the Commission the text of those provisions.

3. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 19

Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.*

Article 20

Addressees

This Directive is addressed to the Member States.

Done at Brussels, [...]

For the European Parliament	*For the Council*
The President	*The President*
[...]	*[...]*

Udenrigsministeriet

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SVAR PÅ UDVALGSSPØRGSMÅL

Patientrettigheder

Til underretning for Folketingets Europaudvalg vedlægges Ministeriet for Sundhed og Forebyggelses besvarelse af spørgsmål nr. 1 og 2 ad KOM (2008) 0414 af den 9. oktober 2009 om forslag til Europa-Parlamentets og Rådets direktiv om patientrettigheder i forbindelse med grænseoverskridende sundhedsydelser.

Per Stig Møller

Folketingets Europaudvalg

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Folketingets Europaudvalg har den 9. oktober stillet følgende spørgsmål nr. 2 (Alm. del) til udenrigsministeren, som hermed besvares. Spørgsmålet er stillet efter ønske fra Lone Dybkjær (RV).

KOM (2008) 0414
Forslag til Europa-Parlamentets og Rådets direktiv om patientrettigheder i forbindelse med grænseoverskridende sundhedsydelser

Spørgsmål nr. 2:

"Ministeren bedes - i forlængelse af Europaudvalgets møde den 2. oktober 2009 - oversende et notat, der redegør for, hvordan man forventer, at man vil fastsætte prisen på diverse sundhedsydelser - dvs. hvordan man vil fastsætte det beløb, som en dansk patient vil kunne få dækket eller refunderet til behandling i en anden medlemsstat."

Svar:

Jeg henviser til det notat, som udvalget har modtaget i forbindelse med min besvarelse af spørgsmål 1. Notatet omfatter et afsnit til besvarelse af udvalgets spørgsmål 2 vedrørende fastsættelsen af det beløb, som en dansk patient vil kunne få refunderet i forbindelse med behandling i en anden medlemsstat (afsnit 7).

Med venlig hilsen

Jakob Axel Nielsen / Hanne Findsen