Consultation concernant une action communautaire dans le domaine des services de santé Communication de la Commission du 26 septembre 2006

Réponse de la Belgique

Avant-propos

La Belgique accueille favorablement la Communication de la Commission et attache une importance toute particulière à cette consultation. Le débat sur les services de santé est déterminant pour l'orientation que suivra l'UE dans les années à venir. Les services sociaux d'intérêt général et la stratégie relative aux soins de santé figurent au nombre des thèmes essentiels pour l'année 2007. Ces dossiers doivent être de préférence reliés.

Selon le point de vue de la Belgique, l'ampleur de l'agenda doit être telle qu'elle permette de s'attaquer à l'ensemble des défis majeurs et d'y répondre. La Belgique considère ainsi qu'il importe non seulement de résoudre la problématique des prestations transfrontalières de soins mais également la question fondamentale de la relation entre la spécificité du secteur des soins de santé, entre autres l'aspect de la solidarité, d'une part, et l'application des dispositions régissant le marché intérieur et les règles de la concurrence, d'autre part.

La Belgique a dès lors organisé une large concertation autour des 9 questions, à laquelle ont été associés les différents acteurs du secteur des soins de santé. Le présent document en est la relation écrite. En annexe à cette réponse belge officielle à cet exercice de consultation, la Belgique transmet également une étude, qui ne lie pas le gouvernement belge, mais qui a comme objectif de nourrir le débat européen, afin d'aller à la rencontre des différentes préoccupations qui ont été formulées.

Lignes de force de la réponse de la Belgique

I. Mobilité

La jurisprudence de la Cour de justice des Communautés européennes relative au remboursement de soins dispensés à l'étranger doit être codifiée et précisée à certains égards. Une directive doit clarifier certains principes et conditions applicables lors de la prise en charge de prestations dispensées dans un Etat membre autre que l'Etat compétent. Cette directive doit également définir une politique d'encadrement pour assurer le bon déroulement de la mobilité des patients et des praticiens professionnels. Le Règlement (CEE) N° 1408/71 relatif à la coordination des régimes de sécurité sociale devra être adapté aux principes ainsi énoncés.

II. Protection de la spécificité du secteur des services de santé

Aujourd'hui, ce n'est pas tant le phénomène de la mobilité des patients/praticiens professionnels qui met sous pression les systèmes de santé et les régimes de sécurité sociale. Les arrêts de la Cour ont introduit plus explicitement que jamais le marché intérieur dans l'organisation des soins de santé. Toutefois, eu égard au caractère spécifique et aux exigences de qualité propres au secteur des soins de santé, des difficultés surgissent parfois au niveau de l'application de notions telles que la libre circulation, la concurrence, l'aide de l'État, …

Il s'agit de savoir comment conserver et continuer à améliorer un niveau élevé de protection de la santé, la cohésion sociale, la protection sociale et la justice sociale, comme le précise le Traité CE, tout en réconciliant les principes économiques fondamentaux de l'UE et les valeurs et principes communs qui fondent les systèmes nationaux de santé dans l'ensemble de l'UE. Une approche spécifique des services de santé est requise afin de fournir une sécurité juridique accrue aux autorités chargées de réglementer, aux acquéreurs, aux prestataires et aux patients, et de garantir que les autorités sanitaires puissent conserver leur capacité décisionnelle dans le cadre de leurs systèmes. En outre, il convient non seulement de garantir la capacité de pilotage des pouvoirs publics, mais aussi et surtout de défendre la cohérence de chaque système de santé, et ce dans l'esprit du principe de subsidiarité.

Question 1: quelles sont les retombées actuelles (à l'échelon local, régional et national) de la prestation transfrontalière de soins sur l'accessibilité aux systèmes de soins ainsi que sur la qualité et la viabilité financière de ces systèmes et comment ces répercussions sont-elles susceptibles d'évoluer ?

En ce qui concerne l'impact direct, nous constatons que la mobilité des patients depuis et vers la Belgique est plus importante que dans la plupart des autres Etats membres de l'UE. De plus, la Belgique est un véritable « importateur » net de patients étrangers. Selon l'enquête réalisée par la Commission européenne en 2000, la Belgique était l'Etat membre ayant le nombre le plus élevé de patients traités pour des soins planifiés[12]. Les flux de patients vers la Belgique, comme vers les autres pays, restent cependant marginaux. En 2002, les patients étrangers non domiciliés en Belgique ne représentaient que 0,58% du nombre total des hospitalisations. C'est en provenance des Pays-Bas que vient le plus grand afflux. Ce pays représentait environ 60% des patients étrangers. En Flandre, les patients domiciliés aux Pays-Bas représentent jusqu'à 87 % des hospitalisations de patients étrangers. L'afflux de patients en provenance des Pays-Bas en Belgique est un phénomène relativement récent qui prend de l'extension. Le nombre de patients E112 ayant été traités en Belgique entre 1998 et 2003 a fortement augmenté (de 10.773 à 22.333). Cette augmentation est due pour une grande partie à l'afflux de patients néerlandais E112

[1] European Commission (2003) *Commission staff working paper "Report on the application of internal market rules to health services - Implementation by the Member States of the Court's Jurisprudence", SEC (2003) 900 of 28 July 2003 (http://europa.eu.int/comm/internal_market/en/services/services/docs/2003-report-health-care_en.pdf)*

[2] Ce constat a été confirmé dans le *Summary paper on Common principles of care, from the Mapping Exercise of the High Level Group on health care services* (doc. HLG/CBH/2006/4/4 du 3 novembre 2006), *http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/high_level_wg_003_en.pdf*

(de 3.970 à 12.503). De plus, en 2003 un certain nombre de patients néerlandais ont été traités en Belgique dans le cadre d'un contrat conclu par leur organisme assureur avec des hôpitaux belges[3]. Quoique ce phénomène soit plutôt limité à l'échelle nationale, il peut toutefois concerner des hôpitaux et des départements hospitaliers spécifiques. C'est ainsi que dans un hôpital belge bien déterminé, 9,3% des patients du département de chirurgie étaient d'origine étrangère[4]. Ces chiffres illustrent également que des initiatives d'intervenants étrangers, tels que des organismes d'assurance maladie néerlandais, visant à acheter des soins en Belgique, sont susceptibles d'entraîner à court terme des modifications importantes au niveau des flux de patients.

A ce jour, il n'y a aucune indication selon laquelle ces flux de patients compromettraient l'accessibilité, la viabilité financière ou la qualité des soins de santé en Belgique. L'afflux de patients étrangers en Belgique a cependant fortement contribué à l'organisation d'un circuit parallèle de soins spécifiquement dédié à des patients étrangers et pratiquant des prix particuliers. Par ailleurs, les hôpitaux accueillant de nombreux patients étrangers lancent un appel toujours plus pressant afin d'obtenir des autorités un financement supplémentaire. On ne peut en effet pas oublier que la capacité de prise en charge d'un système de soins de santé ne se mesure pas uniquement en termes de lits disponibles. De plus en plus, la capacité disponible du système des soins de santé est mesurée en fonction de la main d'œuvre qualifiée disponible et en fonction de l'encadrement nécessaire pour chaque patient.

Il faudrait éviter un scénario tel que: dès lors que le système sera confronté à une demande étrangère trop importante de soins, laquelle n'aura pas été incorporée dans la programmation effectuée sur la base des besoins belges, des listes d'attente apparaîtront et l'accessibilité ne pourra plus être assurée (voir également question 5). Le risque existe donc (principalement dans la partie francophone du pays) de se trouver en présence d'une insuffisance de maisons de repos et d'établissements accueillant des personnes handicapées, et ce en raison de l'augmentation croissante du nombre de pensionnés (de nationalité française) qui résident en permanence dans des maisons de repos en Belgique et dans des maisons de repos et de soins, ainsi que du nombre de personnes (toujours de nationalité française) handicapées qui sont accueillies dans des institutions belges.

L'accessibilité des soins pour les patients belges ne peut pas être compromise. Les opportunités qui existent au niveau international doivent être saisies, pourvu que les droits des patients belges ne soient pas compromis (ex. facturation) et pour autant que ceci puisse être intégré dans le fonctionnement des systèmes existants.

Les autorités belges suivent dès lors attentivement la chose. Selon la Belgique, il est d'une extrême importance que la mobilité existante se déroule de manière ordonnée et qu'il y soit répondu au sein des systèmes de santé tels qu'ils sont organisés par les Etats membres. Dans certaines régions, il s'avère que les partenaires locaux ont parfois organisé depuis plusieurs années déjà une collaboration entre les structures de

[3] 4.617 assurés d'un organisme assureur néerlandais bien déterminé ont été traités en Belgique; les données d'autres organismes assureurs ne sont pas disponibles.

[4] Glinos, I.A., Boffin, N. and Baeten, R. (2005), *Contracting Cross-border Care in Belgian Hospitals: An Analysis of Belgian, Dutch and English Stakeholder Perspectives*, Observatoire social européen, Brussels.

soins pour accueillir des patients à la recherche de prestations transfrontalières de soins. Ces initiatives ont crû spontanément et ont été motivées par le souci de continuer à offrir un traitement de qualité et d'un prix abordable à toute personne nécessitant des soins. Il est souhaitable que les autorités des Etats membres concernés soient pleinement impliquées dans ces initiatives. Cela suppose la disponibilité d'informations complètes sur les flux de patients et sur les prix pratiqués, ainsi qu'un bon monitoring des évolutions.

Question 2: quelles sont les clarifications juridiques spécifiques et les informations pratiques requises – et par qui (par exemple autorité, acquéreurs, prestataires, patients)°- pour que des prestations transfrontalières de soins sûres, efficaces et de qualité puissent être fournies ?

2.1. Clarifications juridiques

Une plus grande sécurité juridique du **point de vue du patient** implique dans un premier temps que les arrêts de la Cour relatifs à la prise en charge de soins dispensés à l'étranger soient codifiés et, sur certains points, expliqués plus avant. La Belgique applique cette jurisprudence.

Un des points cruciaux à éclaircir est celui de la définition des soins pour lesquels une autorisation peut être exigée aux fins de prise en charge de soins reçus dans un Etat membre autre que l'Etat compétent. La CJCE fait référence à des soins hospitaliers . Elle reconnaît qu'un régime d'autorisation préalable se justifie lorsque les soins concernés nécessitent des coûts d'investissement élevés et donc une planification nationale.

Il y a lieu de préciser davantage l'ensemble des soins dont la prise en charge reste soumise à une autorisation préalable, à la lumière de la justification, considérée comme valide par la Cour, du maintien de l'équilibre financier d'un régime national de sécurité sociale.

Il convient également de clarifier davantage la manière dont est calculé le prix de la prestation de soins: les coûts d'investissement sont-ils incorporés dans le prix? Les prix sont-ils du type "all in", calculés pour une période de traitement ou une prestation, etc.

En parallèle, la notion d'autorisation préalable pourra également être envisagée dans une approche plus extensive. Par exemple, prévoir que la délivrance de l'autorisation préalable ne pourra être refusée lorsque la demande se rapporte à une zone géographique donnée (bassin de soins), dans le cadre de projets transfrontaliers, ou vise l'accès à un centre de référence (dans le traitement de maladies orphelines, par exemple).

Une attention particulière peut également être apportée à d'autres motifs pouvant jouer un rôle dans la demande d'autorisation pour un traitement à l'étranger comme la langue, la proximité de la famille et la distance.
En outre, les **praticiens professionnels et les établissements de soins** qui veulent conclure des contrats sur base transfrontalière sont confrontés à bon nombre

d'obstacles juridiques, qui ont trait aux différences existant d'un pays à l'autre aux niveaux suivants : l'organisation des soins de santé, la législation applicable en matière de planification, la mobilité du personnel soignant et la qualité et la sécurité des soins dispensés, ainsi que les modalités relatives à la prise en charge, par les différents régimes de sécurité sociale, des soins dispensés à l'étranger à leurs assurés sociaux.

Quant aux pratiques des **organismes assureurs**, il faut se demander dans quelle mesure les contrats d'exclusivité qu'ils concluent avec des prestataires de soins sont conformes aux réglementations européennes.

Une plus grande sécurité juridique n'est pas seulement nécessaire à l'égard des patients et des prestataires de soins, elle l'est également à l'égard des **autorités concernées**. Une question cruciale à cet égard est de savoir si les Etats membres peuvent imposer les mêmes conditions à des prestataires étrangers qu'aux prestataires de soins nationaux (comme le système de renvoi, les conditions de prescription, les exigences de coût-efficacité des soins, les mécanismes de remboursement, composition du prix, etc.).

A titre d'information, la Belgique a joué un rôle de pionner au sein de l'Union européenne en ce qui concerne l'organisation de la mobilité des patients, au moyen d' accords cadres avec l'Angleterre et la France. Ces accords s'inscrivent dans une logique de complémentarité. Ils peuvent encadrer l'achat de soins en Belgique (accord avec Royaume Uni), dans les limites de la surcapacité, dans le cadre légal et aux tarifs belges ou, comme dans le cas de l'accord sanitaire avec la France, renforcer le tissu sanitaire de la région frontalière par un remaillage des capacités d'intervention de part et d'autre de la frontière qui permet au patient d'accéder à une offre de soins de proximité.

2.2. Points pratiques

Par ailleurs, il est également important pour le patient que l'information nécessaire soit disponible et que tout se déroule dans la transparence, que les droits et les devoirs de toutes les parties concernées (patients, prestataires de soins, hôpitaux, …) soient clairs et que la continuité des soins soit garantie. Les expériences existantes aux niveaux bilatéral et local peuvent fournir un *input* à cet égard.

Que ce soit via internet ou par le biais d'autres canaux d'information, les patients et les prestataires de soins ont besoin d'une **information** synoptique et validée sur la santé, les soins et les médicaments. La diffusion d'informations via internet nécessite une attention particulière. Les sites internet devront être conformes à des règles uniformes qui devront être déterminées et contrôlées sur le plan européen.

Pour ce qui est de la communication d'informations par les Etats membres eux-mêmes, la Belgique est d'avis que l'idée d'un guichet unique n'est pas réalisable en pratique, si elle implique que tout Etat membre doit pouvoir donner à ses ressortissants *toutes* les informations, sur n'importe quel autre système au sein de l'Union européenne. L'Etat membre est cependant responsable de la communication, aux assurés sociaux, d'une information claire sur les procédures et les conditions régissant l'accès aux soins transfrontaliers ; il doit également informer les patients sur

le système national et orienter les patients vers des points d'information dans d'autres Etats membres.

La **transparence** est une autre notion clé. Les pharmaciens (et les médecins) ont besoin d'une base de données européenne qui rassemble, de manière exhaustive et validée, des informations sur tous les médicaments :

- Identité (codification) et contenu (INN, dose, quantité…)
- Disponibilité
- Prix (transparence), tant le prix ex-factory ou d'usine que le prix public
- Remboursement
- Statut légal (mise sous prescription…)

Une circulation plus libre des ordonnances est un second élément dans le contexte de la transparence. Les ordonnances délivrées dans un autre Etat membre font trop souvent problème. Pour promouvoir la libre circulation des ordonnances, un système devra être mis au point qui garantisse l'authenticité de l'ordonnance et offre les garanties nécessaires sur le plan de l'identité, de la compétence/qualité du médecin prescripteur (en ce compris faire en sorte que l'accessibilité soit garantie si une concertation s'impose). La prescription en DCI (INN/DCI) est un système utile et faciliteur dans ce contexte.

Faire toute la clarté sur les **droits et obligations** de toutes les parties concernées est de nature à promouvoir des soins de santé transfrontaliers sûrs, de qualité et efficaces. L'un des aspects a trait aux droits du patient. Cette notion est considérée au sens large en Belgique et couvre bien plus que les indemnisations financières auxquelles peut éventuellement prétendre un patient. La loi du 22 août 2002 relative aux droits du patient, qui est entrée en vigueur le 6 octobre 2002, détermine les droits du patient d'une manière claire, dans le contexte de la relation individuelle entre le patient et le praticien professionnel. Il s'agit, entre autres, du droit à des prestations de qualité, du droit au libre choix du praticien professionnel, du droit au soulagement de la douleur, du droit à l'information sur l'état de santé, du droit au consentement à toute intervention d'un praticien professionnel, des droits relatifs au dossier de patient, du droit à la protection de la vie privée et du droit d'introduire une plainte auprès de la fonction de médiation compétente.

En ce qui concerne la sécurité et la qualité des soins de santé, en rapport avec la libre circulation des prestataires de soins, l'échange d'informations entre les Etats membres est important dans le cas où une interdiction professionnelle serait prononcée dans l'un des Etats membres (quelle qu'en soit la raison) à l'encontre d'un praticien professionnel. L'attraction des praticiens doit également se dérouler d'une manière éthique justifiée au regard du débat sur la migration et le développement.

Le dossier de patient est un instrument important quand il s'agit d'assurer la continuité des soins. Pour promouvoir l'échange de données entre les prestataires de soins, des normes doivent être déterminées et mises à disposition pour rendre possible la constitution de dossiers de patient partagés dans le respect de la législation sur la protection de la vie privée.

Question 3: quels sont les domaines (surveillance clinique, responsabilité financière, etc.) devant relever de la responsabilité des autorités de chacun des Etats concernés ? Ces domaines varient-ils en fonction des différents types de prestation transfrontalière de soins décrits au point 2.2 ci-dessus ?

C'est avant tout le pays où sont dispensés les soins qui assume la responsabilité d'un déroulement dans des conditions de sécurité et d'une réglementation des responsabilités des parties concernées.

Le contrôle et l'organisation des services de soins de santé relèvent donc de la responsabilité de l'Etat membre dans lequel le service est dispensé, indépendamment de la nationalité du prestataire de soins, du patient ou de l'organisme de paiement. Le prestataire de soins est, de toute évidence, responsable lui-même des soins qu'il dispense.

La Belgique est favorable à ce que les Etats Membres collaborent d'une manière dynamique sur la qualité. Cela peut se dérouler via des procédures de bench marking et l'échange des best practices. La normalisation dans cette matière n'est pas appropriée.

La télémédecine est une forme particulière de mobilité : sur la base du principe des soins hospitaliers, il est souhaitable que la responsabilité soit assumée par le praticien posant son diagnostic.

Question 4: qui devrait être chargé de garantir la sécurité des patients en cas de prestation transfrontalière de soins ? Comment garantir des voies de recours aux patients ayant subi des préjudices ?

Un point important dans le domaine de la prestation transfrontalière de soins a trait à la problématique de la responsabilité médicale. Plus particulièrement, il n'est pas toujours évident pour le patient de déterminer quelle est la législation applicable en cas de préjudice ou de faute (le droit du pays destinataire ou le droit du pays d'origine du patient), quel est le tribunal territorialement compétent, et comment se présente la possibilité éventuelle de conclure un accord à ce sujet avec le prestataire de soins.

Dans tous les Etats membres, les questions de ce type relèvent de leur propre droit international privé. Dans cette branche du droit, le juge compétent sur le plan international pour les litiges transfrontaliers est désigné et le type de droit applicable à un rapport juridique transfrontalier déterminé est identifié. Chaque pays a ses propres règles de droit international privé, à l'exception des cas dans lesquels elles ont été uniformisées par le biais d'une législation européenne ou d'engagements internationaux contraignants, fixés par des conventions bilatérales ou multilatérales.

Dans la plupart des cas, les règles à appliquer seront celles du pays où les soins sont dispensés. Cela implique que celui qui se rend à l'étranger se doit de s'informer au préalable, qu'il s'agisse du patient ou du prestataire de soins (cette règle s'applique aussi dans le but de protéger les patients soignés dans leur propre pays par des prestataires de soins étrangers "mobiles".) La Belgique est d'avis qu'il s'agit là de la meilleure approche du problème.

Mais le fait est que cette matière est particulièrement complexe et n'est claire, ni pour le patient, ni pour le prestataire de soins. Il appartient par conséquent aux autorités publiques de diffuser des informations exactes en la matière. La distinction entre les systèmes dits "sans faute" ("no-fault systems") et ceux qui sont basés sur l'existence de la faute doit, elle aussi, être précisée.

Question 5 : que faut-il faire pour que le traitement des patients originaires d'autres Etats membres soit compatible avec la fourniture d'un service médical et hospitalier équilibré accessible à tous (dédommagement financier pour leur traitement dans le pays "destinataire" par exemple)?

La Belgique partage totalement le point de vue exprimé sous le point 3.1.4. selon lequel il convient de davantage clarifier les possibilités dont dispose l'Etat membre accueillant le patient à soigner (le "pays destinataire") pour s'assurer que le traitement de patients originaires d'autres Etats membres ne l'empêchera pas de garantir des soins de santé équilibrés et ouverts à tous et ne nuira pas à la viabilité générale de son système de santé (sous l'angle par exemple de l'organisation et de la fourniture des services).

En Belgique, les soins de santé sont organisés par la mise en oeuvre de trois instruments : programmation, agrément et financement. Ajoutons l'existence d'un vaste régime de conventions. Ces différents mécanismes permettent de garantir la qualité, l'accessibilité et la viabilité des soins dispensés dans le contexte des établissements et autres équipements de soins de santé belges.

La programmation implique la détermination, au niveau fédéral, en fonction des besoins nationaux de la population et des exigences d'une gestion saine, et compte tenu des perspectives d'avenir, le nombre d'hôpitaux, de services hospitaliers, de sections et fonctions hospitalières, de lits hospitaliers … dont il faudra disposer. La méthode appliquée à cet effet se compose de règles et de formules comptables et a comme point de départ des données démographiques, la structure des âges, le taux de morbidité, la répartition géographique, …

Les autorités établissent également des normes d'accréditation (« agrément »), accordent l'accréditation et contrôlent le respect des ces normes. Pour les hôpitaux, ces normes concernent par exemple l'organisation générale des hôpitaux (niveau minimum d'activité, capacité minimum exigée au niveau des lits, des programmes de soins, …) et l'organisation et le fonctionnement des diverses sortes de services (exigences d'équipement technique, médicale, paramédical et de personnel soignant …). De cette manière une qualité minimum est garantie.

La vulnérabilité d'un tel système est claire : au moment où le régime est confronté à une demande trop importante de soins, formulée par des patients étrangers - soins qui n'ont pas été pris en considération dans la programmation qui est basée sur des besoins belges - l'accessibilité risque de ne plus pouvoir être garantie. Il appartient aux Etats membres de faire un choix entre le libre choix et les aspirations d'un patient individuel, d'une part, et une éventuelle limitation de cette liberté en fonction de la volonté de garantir, à long terme, des soins de qualité à l'ensemble de la population, d'autre part.

Par ailleurs, un prestataire de soins (voir réponse à la question 1) doit respecter les mêmes règles tarifaires vis-à-vis de tous ses patients, qu'ils soient belges ou étrangers. Cela stimule l'accessibilité sans pour autant encourager les praticiens à donner la préférence aux patients étrangers. Voir réponse à la question 1.
La Belgique estime dès lors qu'il est crucial que la mobilité existante s'organise de manière ordonnée et soit intégrée dans les systèmes de soins de santé des Etats membres. Dans ce contexte, il doit être possible pour les Etats membres :

- de limiter l'afflux de patient à la surcapacité éventuelle ;
- d'interdire les systèmes de prix différenciés en contraignant les prestataires de soins à appliquer les mêmes règles tarifaires aux patients nationaux et de l'Union Européenne ;
- de conclure des accords au sujet des frais d'investissement et infrastructures à prendre en charge par les autorités respectives;
- de garantir l'accessibilité des soins aux propres patients (prioritisation) ;
- de rassembler des données comparables concernant la mobilité des patients, dans le cadre du Règlement 1408/71, mais également dans le contexte du 'block purchasing' et de la mobilité individuelle.

La Belgique est également favorable à la conclusion d'accords bilatéraux entre les Etats membres expéditeurs et destinataires portant sur les prix, le droit applicable, les nombres, le transfert d'information sur les contrats existants et leur contenu afin de mieux encadrer les initiatives locales. Les principes et les lignes directrices de l'achat de traitements à l'étranger, comme établis en novembre 2005 par le Groupe de haut niveau sur les services de santé et les soins médicaux, devraient être intégrés dans un instrument juridique qui peut service de cadre à ces accords bilatéraux.

Question 6 : d'autres questions sur la circulation des professionnels de la santé ou l'établissement de prestataires de soins qui n'auraient pas encore été traitées dans la législation communautaire devraient-elles être évoquées dans le contexte précis des services de santé ?

En ce qui concerne les prestataires de soins, la question se pose de savoir si et dans quelles conditions, les prestataires étrangers peuvent adhérer aux régimes nationaux de conventions collectives entre les prestataires de soins et les organismes payeurs statutaires des soins de santé. Si les prestataires de soins étrangers ont le droit d'adhérer à ces conventions, il n'est pas clair comment les organismes payeurs des frais de soins de santé pourront contrôler la conformité des soins dispensés à l'étranger. Des règles nationales prises sur base des besoins en soins peuvent-elles justifier la limitation de l'accès des prestataires de soins étrangers aux régimes de conventions ? Il s'agit également de faire toute la clarté sur la question de savoir dans quelle mesure différents tarifs de remboursement peuvent (continuer à) coexister pour les prestataires de soins qui ont adhéré aux conventions collectives et ceux qui n'y ont pas adhéré (en Belgique et à l'étranger).

Les praticiens infirmiers actifs dans le secteur des soins à domicile constituent un autre groupe spécifique de travailleurs de santé "mobiles". Etant donné le vieillissement de la population, ce type de services est essentiel. Dans les régions

frontalières, ils dispensent quotidiennement des soins de l'autre côté de la frontière. Et pourtant, les seuils d'accès sont parfois élevés. Dans les cantons de l'Est (Belgique), on constate ainsi qu'il n'y a pas suffisamment d'infirmiers germanophones pour satisfaire les besoins en termes de soins à domicile. Certains infirmiers allemands sont disposés à franchir la frontière pour soigner les personnes âgées belges à leur domicile ; ils reculent cependant devant la lourdeur de la procédure à suivre pour pouvoir pratiquer en Belgique en tant qu'infirmier allemand.

Question 7 : En ce qui concerne les régimes spécifiques de santé ou de sécurité sociale, y a-t-il encore des points sur lesquels la sécurité juridique doit être améliorée ? Comment les soins de santé transfrontaliers peuvent-ils être simplifiés selon ceux qui sont directement impliquées dans l'accueil de patients provenant d'autres États membres, comme les prestataires de soins et les organismes de sécurité sociale ?

Dans la réponse à la question 5, il a déjà été indiqué que la Belgique estime qu'une plus grande clarté est nécessaire concernant ce que peut faire l'État membre où le traitement se déroule (le pays « destinataire ») pour éviter que le traitement de patients d'autres Etats membres n'entrave des soins de santé équilibrés et accessibles à tous ou que cela n'ébranle la viabilité du système de soins de santé (en termes d'organisation et de fourniture de services, par exemple).

Néanmoins, ce n'est pas tant le phénomène de la mobilité des patients / prestataires de soins qui met aujourd'hui les régimes nationaux de soins de santé et de sécurité sociale sous pression. Les arrêts de la Cour ont introduit plus explicitement que jamais le marché interne dans l'organisation des soins de santé. Toutefois, en conséquence du caractère spécifique et de la qualité propre du secteur des soins de santé, il résulte parfois des difficultés de l'application de notions comme la libre circulation, la concurrence, l'aide de l'État,… . En général, les systèmes de soins de santé se caractérisent non seulement par un financement public, mais aussi par un degré d'intervention publique variable et souvent significatif. En vue de sauvegarder les valeurs et principes communs dans leur organisation des systèmes de soins de santé, les Etats membres devraient continuer de disposer de leur capacité décisionnelle et de certaines responsabilités véritables en matière de réglementation.

La question est de savoir comment maintenir et encore améliorer un niveau élevé de protection en matière de santé, la cohésion sociale, la protection sociale et la justice sociale, comme le précise le Traité CE, tout en réconciliant les principes économiques fondamentaux et les valeurs et principes communs qui étayent les systèmes de soins de santé nationaux dans l'ensemble de l'Union. Pour fournir une plus grande sécurité juridique aux autorités chargées de réglementer, aux acheteurs, aux prestataires et aux patients, et garantir que les autorités sanitaires puissent conserver leur capacité décisionnelle dans le cadre de leurs systèmes, une approche spécifique des services de soins de santé est nécessaire.

Nous estimons que cette approche doit être double : pour certaines matières, les instruments doivent être contraignants sur le plan légal, tandis que pour d'autres, ils peuvent prendre la forme de la coopération entre États membres. Une directive spécifique relative à la santé et aux services de soins de santé garantirait la sécurité

juridique, tandis que la coopération entre États membres pourrait permettre davantage de convergence.

Partant du principe qu'il relève des tâches fondamentales des pouvoirs publics d'organiser une offre efficace de soins de qualité, financièrement abordables et accessibles à tous, il faut profiter de l'occasion de créer également dans ce domaine une plus grande sécurité juridique. En outre, il convient non seulement de garantir la capacité de pilotage des pouvoirs publics, mais aussi et surtout de défendre la cohérence de chaque système.

Ceci a déjà été largement commenté dans le « non paper » en annexe que la Belgique a présenté lors du Conseil EPSCO en juin 2006. Le besoin de sécurité juridique ressort encore des procédures d'infractions entamées récemment par la Commission contre différents États membres, dont la Belgique, qui sont liées à la planification d'établissements de soins de santé.

Question 8: de quelle manière des mesures européennes doivent-elles contribuer à soutenir les systèmes de soins des États membres et les différents acteurs au sein de ces systèmes ? Y a-t-il encore d'autres domaines que ceux mentionnés ci-dessus ?

La Communauté peut effectivement soutenir les États membres dans ce processus en développant la coopération entre eux dans le domaine des soins de santé, en stimulant l'échange des pratiques d'excellence, en collectant des données comparables et en procédant plus systématiquement à des évaluations de l'impact sur les systèmes de santé en cas de nouvelle réglementation.

À cet effet, il convient de constituer un seul comité à partir du Groupe de haut niveau sur les soins de santé et les soins médicaux et le groupe de travail de haut niveau du Conseil ; ce comité pourrait intervenir de manière plus performante et faire rapport directement au conseil des ministres EPSCO, comparable au Comité de protection sociale. Ce comité travaillera en étroite collaboration avec le comité de protection sociale pour le développement et l'approfondissement du volet santé de la méthode ouverte de coordination en matière de protection sociale et d'inclusion sociale. Cette collaboration portera sur les questions d'accessibilité et de soutenabilité financière des systèmes de soins de santé.

Le Groupe de haut niveau a effectué un travail particulièrement précieux sur différents plans. Les lignes directrices sur l'accès aux soins à l'étranger en sont une preuve claire et nette. De nombreux dossiers qui sont étudiés au sein du groupe de haut niveau sont très actuels et très pertinents au niveau politique. Le Groupe de haut niveau fonctionne comme un forum où on peut tester utilement de nouveaux concepts et de nouvelles idées. La Belgique souhaite que cela reste possible à l'avenir. Le Groupe de haut niveau est d'ailleurs le forum approprié pour discuter des résultats de la consultation.
En outre, la Communauté peut encourager et soutenir la coopération internationale sur le terrain. Ainsi, en œuvrant au développement de la profession, les organisations professionnelles de prestataires de soins contribuent de manière significative à la promotion et à la garantie de la qualité des soins. Elles offrent également un soutien

précieux aux praticiens professionnels et aux pouvoirs publics. Il faudrait plus particulièrement encourager et soutenir la coopération entre les organisations nationales (à l'échelon européen) et entre les organisations de différentes disciplines (au niveau des Etats membres).

Question 9 : Quelles ressources sont adéquates pour aborder les différentes questions relatives aux services de soins au niveau de l'UE ? Quelles sont les questions qui doivent être réglementées par le biais de la législation communautaire et quelles questions doivent l'être par des moyens non législatifs ?

La Belgique préconise une stratégie à double orientation.

Pour les points sur lesquels une sécurité juridique accrue est souhaitable, une **directive** relative aux services de santé constitue l'instrument le plus indiqué.

Une directive doit avant tout offrir davantage de sécurité juridique aux Etats membres en garantissant que les autorités santé peuvent maintenir le « steering capacity » sur leurs systèmes. Une approche spécifique sur les services de soins de santé est nécessaire. Il faut profiter de l'occasion de réquilibrer d'une part les principes basés sur l'idée de liberté économique et d'autre part, les principes sur base desquels les soins de santé sont organisés dans les Etats membres telles que la solidarité, l'universalité, l'accessibilité, la qualité, la durabilité financière… En outre, il convient non seulement de garantir la capacité de pilotage des pouvoirs publics, mais aussi et surtout de défendre la cohérence de chaque système.

La jurisprudence de la Cour de Justice des Communautés européennes concernant le remboursement de soins fournis à l'étranger doit être codifiée et précisée sur certains points. Une directive doit également clarifier certains principes applicables lors de la prise en charge de soins dispensés dans un Etat membre autre que l'Etat compétent. La directive doit également définir une politique d'encadrement pour assurer le bon fonctionnement de la mobilité des patients et des praticiens professionnels. Le Règlement (CEE) 1408/71 relatif à la coordination des régimes de sécurité sociale devra être adapté aux principes ainsi énoncés.

À terme, le droit universel à des soins de santé accessibles, de qualité et abordables doit être garanti dans la législation européenne, bien entendu dans le respect du principe de subsidiarité.

En ce qui concerne certains aspects relatifs aux soins de santé, une directive ne constitue pas forcément le seul instrument ou l'instrument le plus approprié. Quoi qu'il en soit, les Etats membres ont manifestement besoin de **coopérer** dans ces matières en vue du respect du patient. La méthode ouverte de coordination est l'un des instruments disponibles pour y parvenir. En effet, il s'agit d'une méthode flexible permettant aux Etats membres de s'accorder sur une mesure de développement commun de politiques par le biais de l'échange des pratiques et la coordination, sans remettre en question la subsidiarité.

NON PAPER

The European Parliament recently adopted the position to exclude healthcare services from the scope of the Directive on services in the internal market. The European Commission endorsed this position in its modified proposal. At the same time the Commission excluded healthcare services from its Communication on social services of general interest and announced a specific initiative in this field.

Discussions on what legal form such an initiative should take and what the scope and the content should be have yet to begin.

1. The need for a sector specific approach

Treaty provisions concerning the internal market and the basic freedoms have an ever growing effect on the very specificity of the healthcare sector. Issues such as patient mobility, establishment of providers, free provision of services and goods are becoming increasingly important.

As described in the recent statement on common values and principles by the 25 Health Ministers of the European Union, healthcare systems throughout Europe share common values and principles that underpin them. Access to healthcare is considered as a fundamental right. Providing equal and fair access for all to a balanced and adequate supply of high-quality treatment is therefore regarded as one of the core tasks of public authorities. They assess the need and thereupon organise their system. It is an assignment undoubtedly related to the general interest. Since health risks and health costs are also very unevenly spread among the population, only systems based on varying measures of public funding or compulsory adherence and contributions based on solidarity can guarantee affordable care to the whole population.

For all these reasons, health systems are generally characterised not only by public financing but also by varying and often considerable degrees of public intervention. In order to safeguard the above-mentioned common values and principles while organising their healthcare systems, Member States should continue to dispose of a steering capacity and some genuine regulatory responsibilities.

Besides, from an economic perspective the healthcare market is characterised by some specificities requiring public intervention. Patients do not necessarily have the knowledge to make an informed decision about the care they need. This information asymmetry between provider and patient leads to a dependency of the patient, and the risk of exploitation of the system through provider induced demand. Furthermore, normal price setting mechanisms based on the balance between supply and demand do not function properly within this sector because the patient is not covering his own cost. This also means that patients and providers have little incentive for the most cost-effective use of the financial means. Health services are sui generis services and therefore require a differentiated approach within the internal market legislative framework.

The question is how to maintain and further enhance a high level of health protection, social cohesion, social protection and social justice as stated in the EC Treaty, while reconciling the EU fundamental economic principles and the common values and principles underpinning the national health systems throughout the Union? In order to provide more legal certainty to the regulating authorities, purchasers, providers and patients, and to guarantee that health authorities can keep the steering capacity over their systems, a specific approach towards healthcare services is needed.

We believe that this approach ought to be twofold: for some issues the instruments have to be legally binding, while for other issues they can take the form of cooperation between Member States. A specific directive concerning health and healthcare services would ensure legal certainty while cooperation between Member States could allow more convergence.

2. A specific directive on healthcare and healthcare services

2.1. The scope of the directive

This directive should cover all healthcare services. To begin with, this encloses the services as excluded from the directive on services in the internal market as defined in the modified proposal of the Commission:

> *"healthcare services whether or not they are provided via healthcare facilities, and regardless of the ways in which they are organised and financed at national level or whether they are public or private."*

This includes inter alia services such as medical, paramedical, mental, pharmaceutical, nursing, physiotherapeutic and care services as a whole, without distinction as to whether or not they are supplied in a health care facility, whether or not they are provided within a national social protection or health insurance system, or whether or not they are financed or organised by the government. Those services encompass amongst others activities in the field of prevention (both screening and prevention), health promotion, diagnosis, treatment, care, rehabilitation, long term (health) care and re-education, and emergency medical aid.

2.2. Structure and content of the directive

The idea behind the directive should be to describe the common values and principles that underpin all healthcare systems in the European Union and outline their objectives, then to give an insight into the different types of instruments public authorities use to properly manage their health care systems and thirdly to identify the conditions under which the use of these instruments is no longer in conformity with the Treaty provisions.

The basic presumption is that in order to organise their healthcare systems, Member States need to dispose of a steering capacity and some genuine regulatory responsibilities. This steering capacity can be translated into a list of tools, instruments that are used as of today to organise health systems throughout the

Union, such as planning, tariff setting mechanisms, authorisation schemes for providers etc… Possibly, the directive could contain an open list of tools, leaving it up to each Member State to decide which instruments it considers appropriate to organise its proper health system.

Furthermore, if within the scope of this directive these instruments are used by Member States in order to safeguard the above-mentioned common values and principles, their use is to be regarded as justified as this constitutes an overriding reason relating to the public interest.

Of course, there are certain limits that have to be respected, relating to principles such as non-discrimination and proportionality. The directive should identify these limits by clarifying how these principles apply to the healthcare sector. The ECJ case law could be an important basis.

In addition, the directive must clarify under what circumstances health care provided for within another member state shall be reimbursed by the country of origin. The patient's right to reimbursement is vital and needs to be carefully balanced. The former article 23 of the Directive on services within the internal market could serve as a basis for this, taking into account the interrelationship with the modified Regulation 1408/71. Only when there is greater clarity can patients be treated according to need and on a non-discriminatory basis and only then can we foresee and maintain the financial sustainability of the national systems. The distinction between hospital and non-hospital care for example has shown to be very complex and must be carefully assessed and elaborated.

Finally, in order to assess the conformity with EU law of national regulations, we call for enhanced cooperation and dialogue between the substantively competent services of the European Commission (DG SANCO and DG Employment, Social Affairs and Equal opportunities) and the national competent authorities of the Member States in order to fully understand the specificities of the national health systems.

3. Cooperation between Member States

For some issues related to healthcare such as patient rights, quality of health care, patient safety, liability and compensation issues, patients right to confidentiality … a directive may not be the only or the most appropriate instrument. Nevertheless there is a clear need for Member States to cooperate on these items in order to respect the patient.

The Open Method of Coordination is one of the instruments available to do so. It is indeed a flexible method allowing Member States to agree to a measure of joint development of policies, by means of exchange of practices and coordination, without calling into question subsidiary.

The putting into place of this coordination mechanism will help those patients seeking care within the union to have access to information about treatment, risks, liability issues etc in the country where treatment is provided for.

federal public service
HEALTH, FOOD CHAIN SAFETY
AND ENVIRONMENT

"Internal market and Health Care: a new balance?"

Study conducted by
Université Libre de Bruxelles
in collaboration with the Katholieke Universiteit Leuven
on the request of
Rudy DEMOTTE
Minister of Public health and Social affairs, Belgium

I. Distribution of Competences For The Organisation of Health Care

1. This issue is directly related to the problem of the allocation of powers between the Community and its Member States. Under Article 5 EC, the powers of the Community are limited to those specifically conferred on it. The Community's obligation to strictly adhere to the principle that its powers are those specifically conferred on it was confirmed by the Court in the famous "tobacco" judgment.[5] All the powers that the Treaty does not specifically confer on the Community remain with the Member States. The Treaty contains neither a general clause nor a systematic power allocation list. The implementation of the competences conferred on the Community is to be found in the material provisions, policy by policy, sector by sector … This results in a very complex entanglement of national and Community competences.[6]

2. Where the Community is competent, this competence is either exclusive or shared with the Member States. The EC Treaty does not refer to Community powers as either exclusive or non-exclusive. Following the Treaty on the European Union, the concept of 'exclusive' competence appeared for the first time in the EC Treaty, namely in the provision relating to the subsidiarity principle (Art. 5(2) EC). Since this concept marks out the implementation of the principle of subsidiarity, it is an extremely important notion.[7]

   The idea of 'exclusive competence' is built upon the European Court of Justice's case law. As a matter of fact, it looks as though the Court distinguishes between competences that are exclusive by nature and those that are exclusive when they are exercised.[8]

   So far, the Court of Justice has recognised exclusive Community competence in four areas: common trade policy, policy on the preservation of maritime resources (since 1 January 1985), monetary policy in the euro zone (as from 1 January 1999) and the conclusion of the new Lugano Convention on Jurisdiction and Enforcement of Judgments in Civil and Commercial Matters.[9]

3. Where the Community is competent, this competence does not *ipso facto* cover the adoption of harmonisation measures. A number of provisions relating to new

[5] C-376/98, *Germany vs European Parliament and Council (Tobacco I)*, Rec. p. 1-8419.
[6] M. Dony, Droit de la Communauté et de l'Union européenne, Ed. de l'ULB, 2001, p. 93.
[7] L. Defalque, Commentaire J.Mégret, 2006, Marché intérieur, Rapprochement des législations, p. 208, No. 387.
[8] K. Lenaerts and P. Van Yperseele, Le principe de subsidiarité et son contexte, C.D.E. 1994, p. 3.
[9] L. Defalque, op. cit., p. 208 and 209, No. 388. The conclusion of the Lugano Convention is an example of ERTA-exclusivity, summarised in Article I-13(2) of the Treaty establishing a Constitution for Europe as *"the conclusion of an international agreement when its conclusion is provided for in a legislative act of the Union or is necessary to enable the Union to exercise its internal competence, or insofar as its conclusion may affect common rules or alter their scope."*

competences, mainly of a non-economic nature, that were conferred on the Community by the Treaty on European Union exclude harmonisation. This is the case for public health (Article 152(4) EC).

However, even if the Community was not given the power to approve harmonisation measures for achieving a given objective, it is allowed to pursue this goal secondarily when trying to reach another objective. This possibility results from the first 'tobacco' judgment.[10] The Court found that the Community legislator was not allowed to refer to Article 95 of the Treaty as a legal basis for harmonisation efforts in the field of public health while this is expressly forbidden. By contrast, any licit harmonisation may have a secondary public health objective.[11] In addition, Article 95(3) of the Treaty obliges the legislator to take as a basis a high level of protection of human health, which gives the Community some margin of appreciation in this area.[12] Therefore, provided that the conditions for recourse to Article 95 as a legal basis are fulfilled, the Community legislator cannot be prevented from relying on that legal basis on the ground that public health protection is a decisive factor in the choices to be made.[13]

> *4. In the field of public health, powers between the Community and its Member States are shared in accordance with the provisions of Article 152 EC that were incorporated into the EC Treaty when the Treaty on the European Union was adopted, together with the subsidiarity principle. This provision states that a high level of human health protection is to be ensured in the definition and implementation of all Community policies and activities.*
>
> Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. (Art. 152(1), second sentence). The Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action (Art. 152(2), first sentence).
>
> *Member States shall in liaison with the Commission, coordinate among themselves their policies and programmes. The Commission may ... take any useful initiative to promote such coordination (Article 152(2), second sentence).*
>
> *The Council, acting in accordance with the procedure referred to in Article 251 shall contribute (...) through adopting incentive measures designed to protect and improve human health, excluding any harmonisation of the laws and regulations of the Member States (Article 152(4c)).*

[10] C-376/98*, Germany v EP and Council ("Tobacco I")*.
[11] L. Defalque, *op. cit.* p. 221, No. 407.
[12] C-210/03, *Swedish Match*, par 46.
[13] C-491/01, *British American Tobacco*, par 62; C-434/02, *Arnold André*, par 32; C-210/03, *Swedish Match*, par 30; C-154/04 and C-155/04*, Alliance for Natural Health*, par 30; recently confirmed by ECJ 12.12.06, C-380/03, *Germany v EP and Council ("Tobacco II")*, par 39 and 92.

Finally, Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care (Article 152(5)).

5. Article 152 EC allocates responsibilities between the Community and Member States while any form of harmonisation is excluded to protect and enhance human health. Community action can only complement national policies and encourage cooperation among Member States with full respect of the responsibilities of Member States for organising and delivering health services and medical care. Clearly, the latter formula is ambiguous because Article 152(5) refers to "*the responsibilities of the Member States for the organisation and delivery of health services and medical care*" and not to the sovereign or exclusive competences of Member States in this matter. However, the Treaty establishing the European Constitution for Europe may serve as a reference for interpreting the allocation of competences between the Community and Member States in these matters. Article I-17 of this Treaty provides that the Union shall have competence to carry out supporting, coordinating or complementary action in the areas of the protection and improvement of human health. Such acts must not entail harmonisation of Member States' laws or regulations (Article I-12.5 of the Treaty establishing a Constitution for Europe).

6. The interpretation of Article 152(5) formed the object of a question referred to the Court of Justice for a preliminary ruling in the Watts case. The seventh question indeed raised the issue whether Member States are required under Article 49 EC and Article 22 of Regulation 14108/71 to pay for hospital expenses made in another Member State without reference to budgetary constraints and, if so, whether this was compatible with Article 152(5) EC.

   *In his conclusions, delivered on 15 December 2005, Advocate General Geelhoed stated that "*seen in the context of Article 152 EC as a whole, the function of the fifth section of this article is to impose a limit on the various activities and policies which can be adopted by the Community in this field. It is not intended to recognise a general exception to obligations under the Treaty based on the responsibilities of the Member States in the health care sector. Rather, it should be read in line with the Court's well-established approach according to which it is recognised that the Member States retain full power to organise their social security systems, but that in exercising these powers they are required to fully respect their obligations under Community law, particularly those related to the fundamental freedoms guaranteed by the EC Treaty" *(par 123)*.

   … (the Court) *has acknowledged in the context of Article 49 EC that the risk of the financial balance of the social security system being undermined may justify such a restriction in so far as this may have consequences for the overall level of public health protection* (par 124).

*The Advocate General goes on to declare that a Member State may take restrictive measures when they directly threaten the viability of the national system, thereby undermining the quality and continuity of the provision of health care in its territory (par 125). The Advocate General seems to allow a "*general policy aimed at maintaining the financial stability of the system*" (par 125).*

*He then states that "*By reconciling the requirements of the freedom to provide hospital services with the vital interests of the Member States in guaranteeing the stability of their national health care systems, the Court has indicated within which limits budgetary limits can be taken into account. This interpretation fully respects the responsibilities of the Member States for the organisation and delivery of health care services and medical care within the meaning of Article 152(5) EC." *(par 126)*

In reply to the seventh prejudicial question in his judgment pronounced on 16 May 2006 in the Watts case,[14] *the Court holds that "*according to Article 152(5) EC, Community action in the field of public health is to fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care." *(par 146)*

"That provision does not, however, exclude the possibility that the Member States may be required under other Treaty provisions, such as Article 49 EC, or Community measures adopted on the basis of other Treaty provisions, such as Article 22 of Regulation No 1408/71, to make adjustments to their national systems of social security. It does not follow that this undermines their sovereign powers in the field." (par 147)

7. In line with this interpretation of Article 152(5) EC, the responsibilities of the Member States for the organisation and delivery of health services and medical care are 'sovereign' responsibilities that have to be exercised with full respect of the provisions of the Treaty, particularly Article 49 EC and the provisions of Regulation no. 1408/71 (and, obviously, also Article 28 EC).

   Member States' responsibilities under Article 152(5) EC seem directly related to those that the Court has bestowed on them in its jurisprudence on the organisation and financing of social security.

   In this respect, it is established case law of the Court of Justice that Community law does not detract from the power of the Member States to organise their social security systems.[15] Given the lack of harmonisation at Community level, it is up to the legislation of individual Member States to lay down the conditions

[14] C-372/04.
[15] C-385/99, *Müller-Fauré*, par 100; C-238/82, *Duphar*, par 16; C-70/95, *Sodemare*, par 27.

governing the grant of social security benefits; yet, when exercising this competence, Member States are required to comply with Community law.[16]

> *In its above-mentioned judgment in the* Müller-Fauré *case of 13 May 2003,*[17] *the Court makes two preliminary remarks. First, achievement of the fundamental freedoms guaranteed by the Treaty inevitably requires Member States to make some adjustments to their national systems of social security. It does not follow that this would undermine their sovereign powers in this field (par 102). Second, a medical service does not cease to be a provision of services because it is paid for by a national health service or by a system providing benefits in kind (par 103). The Court goes on developing its arguments and concludes that removal of the requirement that sickness insurance funds grant prior authorisation to their insured to enable them to receive health care, in particular other than in a hospital, provided in a Member State other than that of affiliation would undermine the essential characteristics of the Netherlands sickness insurance scheme (par 108).*
>
> *8. It seems to follow from the Court's case law that the sovereign authority or the responsibility assigned to the Member States for organising and delivering health services and medical care, as well as for organising and financing their social security systems, may be exercised only if they comply with the Treaty provisions, i.e. that they have to respect,* inter alia*, the free circulation of goods and services as well as the competition rules. Exceptions to these rules may be admitted, notably when they are needed to preserve the essential characteristics or the financial stability of the national system. However, the Court considers that the achievement of the fundamental freedoms guaranteed by the Treaty may oblige Member States to make some adjustments to their national social security system, and it seems that this obligation can be extended to the organisation of health care.*

9. It is common ground that Article 152(5) EC does not prevent the adoption of measures on the basis of EC Treaty provisions that relate to other Community policies than the field of public health. According to Article 95(1) EC, the Community legislator is entitled to take harmonising measures "*which have as their object the establishment and functioning of the internal market*". This means that these measures should actually contribute to the elimination of barriers to the free movement of goods or the freedom to provide services, or to the removal of distortions of competition.[18] Whereas the Court of Justice originally deemed it necessary to verify whether each of these conditions was fulfilled,[19] the requirement of an appreciable distortion of competition is now considered to form a constitutive (and separate) component of an initiative taken under Article 95

[16] See judgments above in note 10.
[17] C-385/99.
[18] C-376/98*, Tobacco I*, par 83, 84 and 95.
[19] C-376/98, *Tobacco I*, par 95-114 EC.

EC.[20] Consequently, if one of the two conditions is fulfilled, Article 95 may be used as the legal basis for the harmonisation measures.

Apart from Article 95 EC, Articles 47(2) and 55 also confer on the Community legislator specific power to improve the functioning of the internal market in the field of services. On those bases, the legislator is entitled to take coordination measures facilitating the taking up and pursuit of service activities and to provide exceptions or limitations justified by the protection of public health.

Provided that the conditions for the use of the legal basis of Article 95, Article 47(2) EC and Article 55 EC are fulfilled, "*the Community legislator cannot be prevented from relying on that legal basis (i.e. art.95) on the ground that public health protection is a decisive factor in the choices to be made.*"[21] It is especially so, since Article 152, par 1 EC states that a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities. Furthermore, Article 95(3) EC requires Community institutions to achieve the objective of a high level of protection of health whenever Article 95 is used as a basis for harmonisation.[22]

10. The fact that the Community legislator can rely upon Article 95 EC however does not imply that the Community has an exclusive competence to regulate economic activities on the internal market.[23] The contemplated Community measure will have to comply with the principle of subsidiarity. According to the Protocol on the application of the principles of subsidiarity and proportionality annexed to the Treaty of Amsterdam, *"... Community measures should leave as much scope for national decision as possible, consistent with securing the aim of the measure and observing the requirements of the Treaty. While respecting Community law, care should be taken to respect well established national arrangements and the organisation and working of Member States' legal systems. Where appropriate and subject to the need for proper enforcement, Community measures should provide Member States with alternative ways to achieve the objectives of the measures."*[24] This means that the measure should be a directive preferably to a regulation. This means also that the objectives of the directive i.e. the facilitation of the free movement of services and of goods should be pursued with respect to the well established health systems organised by the Member states in order to protect and safeguard public health on their respective territory.

[20] C-491/04, *British American Tobacco*, Opinion Advocate General Geelhoed, par 145, 149-151.
[21] C-376/98, *Tobacco I*, par 88.
[22] C-376/98, *Tobacco I*, par 88 and C-491/04, *British American Tobacco*, par 62.
[23] C-491/04, *British American Tobacco*, par 179.
[24] "Protocol (No 30) on the application of the principles of subsidiarity and proportionality" (Amsterdam, 2 October 1997), in *Official Journal of the European Communities (OJEC)*. 10.11.1997, No C 340, p. 105, par 7.

II. Responsibility of Member States to Organise and Deliver Health Services and Medical Care In Accordance With Article 152, Par 5 EC

11. This responsibility of Member States for the organisation and delivery of health services and medical care means that each Member State has the right to choose how its health care system is organised. Even if there is a large diversity of health systems in Europe, all systems are based on the solidarity principle and are characterized by a high degree of public coverage, directly financed through taxes and/or social contributions. Solidarity is expressed in the national policies on the financing of the health care system as well as in a balanced distribution of care according to need.[25] Indeed, each Member State provides a number of regulatory instruments for planning the health care supply, personnel standards in health care institutions, price-fixing mechanisms, referral systems, etc... Through these instruments, each Member State aims to guarantee accessible and reasonably priced health care to every citizen, continuity of care, and patient protection. These instruments are tailored to the specificity of the health care sector: asymmetry of information between the patient and the care provider, the recognition of accessible care for everyone as a fundamental right, the presence of a third public party reimbursing a large part of the health care cost, the need induced by the care providers, and the phenomenon of moral hazard.[26]

12. The list of key mechanisms for the organisation of health care systems in Europe includes:

- Financing mechanisms for the health care system: e.g. collecting social contributions, falling back on tax recoveries and regulating the direct participation of patients in care expenses.

- Setting priorities and allocating resources: these mechanisms are used to adjust health priorities in order to allocate the resources within the limits of the public budget. A system is developed to distribute financial, material or human resources according to the needs. The budget can be established on an overall basis or a sectoral basis - e.g. using limited envelopes and recovery mechanisms (when the envelope has been exceeded).

- The general organisational structure of the health care system:

[25] H. Lewalle, "Systèmes de santé et intégration européenne" in P. Nihoul and A.-C. Simon, *L'Europe et les soins de santé*, Larcier, 2005, p. 38 and 33.
[26] H. Lewalle, "Systèmes de santé et intégration européenne", *l.c.*, p. 29.

- *Authorization schemes* for health care providers, patients (e.g. referral systems) and other parties concerned (including intermediaries).
- *Referral and prescription mechanisms*: including requirements for documents used and procedures to be followed, as well as the obligation for certain intermediary providers to give access to specialist medical care (e.g. the general practitioner acting as a referral physician (= "*GP gatekeeper*")).
- *Competition regulations:* granting monopolies, allocating exclusive or special rights or allocating public money to hospitals.
- *Reimbursement conditions* for costs of medical care.
- *Requirements to ensure that the allocated budget is used for the agreed purposes (f.i. requirement to respect salary and employment conditions* defined in existing collective bargaining agreements).

➢ Measures on quality and cost-effectiveness of health care:

- *Input quality standards:* these may concern infrastructures and equipments, but also the health care providers (cf. accreditation systems for physicians). These standards also include: conditions regarding minimum staffing, continuing vocational training, organisation of *peer reviews* and conditions with respect to the knowledge and use of languages by medical care providers.
- *Process quality standards:* these include requirements concerning care procedures as well as *micro level performance measures* (review of service providers' behaviour based on quality and cost-effectiveness criteria).
- *Output quality standards.*
- *Patient rights:* on the one hand these rights imply the information of patients about their medical condition (direct access to the medical records), the availability of medical treatment, and the existence of complaints procedures. On the other hand, they imply the patients' free consent (including treatment of patients unable to express their consent to medical care) as well as requirements related to the protection of patient data (e.g. through professional secrecy and data protection in transfer situations).
- *Provisions regarding the behaviour of health care providers*: particularly regarding responsibility, disciplinary rules, reserved activities, etc.
- *Requirements linked to the continuity of health care*: enabling to offer care adapted to the patient's needs in a concerted way

and enabling the patient to make a flexible transition between different care providers.

- Restrictions to *advertising and commercial communications* for and by doctors.

➢ Regulating the supply-side and the definition of access to health care:

- *A balanced allocation of the supply-side*: in order to keep up the supply of health care and to ensure universal access to care, the Member States allocate health care supply by establishing national programming and planning standards, taking into account the limits of the public budget. These are quantitative or territorial restrictions in the form of limits based on the population or on a minimum geographical distance between providers: e.g. limiting the number of health care facilities and the number of beds. The volume of medical services is also subjected to regulation by limiting access to the health care professions (at an educational level or the practising of a profession), by accreditation systems for doctors, and by limiting the number of appliances used (e.g. authorization procedures for installing high-technology medical equipment).
- *The definition of the medical supply* funded by public authorities.
- *Waiting lists*: an instrument used for rationalizing demand and setting priorities in the access to supply.
- *Restricting the role of profit seeking providers*: by means of requirements that oblige providers to be set up in a specific legal way, namely in the form of a legal person, a one-man company, a non-profit entity or a company owned exclusively by natural persons.
- *Conditions reserving access to* practising care to specific providers due to the specific nature of the care (e.g. the provision of pharmaceutical care).
- *Promoting the coordination and cooperation of care*: between the care providers and the different levels of care by developing integrated care, dividing tasks and defining more clearly the providers' activities.
- The obligation for the care provider to *offer certain specific kinds of care together with other care* (e.g. the obligation for hospitals to set up a reanimation ward if run an emergency service).

➢ The introduction of *special contract-based systems* between health care providers and health care payers and establishing prices and price mechanisms: Imposing compulsory minimum and/or maximum tariffs for medical and paramedical services (see the negotiated tariffs in the

conventions) and establishing prices for medication and medical equipment, as well as introducing price mechanisms (see reimbursement systems).

III. The Application of EC Treaty Rules on Internal Market and on Competition

A. Introduction

13. These instruments imply a strong regulation of the health care market and it is clear that, insofar as these instruments introduce market and competition mechanisms in the national health care systems, those systems will be subject to Community law, such as the rules on the internal market and the rules of competition, including rules on state aid.[27]

B. Free movement of services

14. EC Treaty provisions on internal market and competition, including state aid rules only apply to activities insofar they are economic. According to the ECJ case law, an economic activity is an activity which consists in offering goods and services on a given market.[28] Hence, Treaty provisions on the free movement of services (Article 49-50 EC) and the freedom of establishment (Article 43 EC) only apply to services in so far they are of an economic nature. This is expressed in Article 50 EC, according to which services within the meaning of the EC Treaty are normally provided for remuneration,[29] the latter being a condition for the application of the free movement of services.

    It is established case-law that health care services provided for consideration, fall within the scope of Article 50 EC.[30] The special nature of these services does not remove them from the ambit of the fundamental principle of the freedom of movement.[31] For the application of Articles 49-50 EC, it does not matter whether care is provided in a hospital environment or is provided outside such an

[27] See e.g. Y. Jorens, M. Coucheir and F. Van Overmeiren, Access to Health Care in an Internal Market: Impact for Statutory and Complementary Systems, Ghent University, Department of Social Law, 2005.
[28] See e.g. C-180/98-C184/98, *Pavlov a.o.*, par 75. This case concerned the classification of an occupational pension fund as an undertaking (i.e. for the purpose of the applicability of EC competition rules).
[29] It follows from the Court's judgement in the *Wirth* case that services financed *essentially* out of public funds do not constitute services within the meaning of Article 50 EC (C-109/92, Wirth, para 15-19) (see K. Lenaerts en P. Van Nuffel; R. Bray (ed.), Constitutional Law of the European Union, London, 2nd edition, Sweet & Maxwell, 2005, p 227). However, this has been greatly nuanced in respect of medical services (see below).
[30] See e.g. C-372/04, *Watts*, par 86.
[31] C-158/96, *Kohll*, par 20.

environment.[32] Moreover, the Court ruled that, in order to be subject to the EC provisions relating to services, it does not matter whether the patient pays the cost for care and asks for reimbursement or whether the sickness fund or the national budget pays the care provider directly.[33] Even medical services under a national health system financed mainly by public taxation fall within the scope of the EC Treaty provisions on free movement. In the Watts case (C 372/04), the Court held that: "*The fact that reimbursement of the hospital treatment in question is subsequently sought from a national health service such as that in question in the main proceedings does not mean that the rules on the freedom to provide services guaranteed by the Treaty do not apply (see to that effect Smits and Peerbooms, paragraph 55, and Müller-Fauré and van Riet, paragraph 39). It has already been held that a supply of medical services does not cease to be a supply of services within the meaning of Article 49 EC on the ground that the patient, after paying the foreign supplier for the treatment received, subsequently seeks the reimbursement of that treatment from a national health service (see Müller-Fauré and van Riet, paragraph 103)." (par 89)*

"It must therefore be found that Article 49 EC applies where a patient such as Mrs Watts receives medical services in a hospital environment for consideration in a Member State other than her State of residence, regardless of the way in which the national system with which that person is registered and from which reimbursement of the cost of those services is subsequently sought operates." (par 90)

The Court then concluded: *"It must therefore be found that a situation such as that which gave rise to the dispute in the main proceedings, in which a person whose state of health necessitates hospital treatment goes to another Member State and there receives the treatment in question for consideration, falls within the scope of the Treaty provisions on the freedom to provide services, there being no need in the present case to determine whether the provision of hospital treatment in the context of a national health service such as the NHS is in itself a service within the meaning of those provisions."* (par 91)

15. The impact of EC Treaty provisions on free movement on national health care systems has been demonstrated through ECJ case law dealing with the compatibility of national authorisation schemes for the reimbursement of costs for medical treatment abroad. According to the Court, it is beyond any doubt that such an authorisation scheme *"constitutes, both for those patients and for service providers, an obstacle to the freedom to provide services."*[34] However, the Court's answer to the question whether such an authorisation scheme is a justified barrier

[32] E.g. C-157/99, *Geraets-Smits and Peerbooms*, par 53.
[33] C-385/99 *Muller Fauré*, par 103.
[34] C-372/04, *Watts*, par 98, see also C-175/99, *Smits and Peerbooms*, par 69 and C-385/99, *Müller-Fauré and van Riet*, par 44.

to the free movement of services directly depends on whether medical care is provided in a hospital environment (intramural care) or not (extramural care).

16. With regard to extramural care, the Court clearly stated that national authorisation schemes are not justified. Faced with the question whether or not the Dutch system of prior authorisation for reimbursement was justified in view of the risk of seriously undermining the financial balance of the Netherlands social security system, the Court concluded that *"... the documents before the Court do not indicate that removal of the requirement for prior authorisation for that type of care would give rise to patients travelling to other countries in such large numbers, despite linguistic barriers, geographic distance, the cost of staying abroad and lack of information about the kind of care provided there, that the financial balance of the Netherlands social security system would be seriously upset and that, as a result, the overall level of public-health protection would be jeopardised - which might constitute proper justification for a barrier to the fundamental principle of freedom to provide services.*[35]

17. With regard to intramural care, the Court has repeatedly stated that a national authorisation scheme for the reimbursement of costs for medical care abroad appears to be a necessary and reasonable measure and thus constitutes a justified barrier to the free movement of services. In this respect, the Court explicitly refers to the need of hospital planning which covers *"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."*

    The Court then continues: *"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 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. 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."*[36]

    The recognition of a national authorisation scheme for reimbursement as a justified barrier to the free movement of services does not mean that the conditions for granting an authorisation must not be objectively defined by the relevant national health authorities. According to the Court, *"... it must in any event be based on objective, non-discriminatory criteria which are known in*

[35] C-385/99, *Müller-Fauré*, par 95.
[36] C-372/04, *Watts*, par 108-9, C-385/99, *Müller-Fauré*, par 77, 79-80 and C-157/99, *Smits and Peerbooms*, par 78-9.

advance, in such a way as to circumscribe the exercise of the national authorities' discretion, so that it is not used arbitrarily. Such a system must furthermore be based on a procedural system which is easily accessible and capable of ensuring that a request for authorisation will be dealt with objectively and impartially within a reasonable time and refusals to grant authorisation must also be capable of being challenged in judicial or quasi-judicial proceedings."[37]

It also implies that a refusal to grant authorisation has to refer to these objective criteria as well as the reasoning based thereupon. In the Watts case, the Court has pointed out that a refusal *"... cannot be based merely on the existence of waiting lists enabling the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out in the individual case in question an objective medical assessment of the patient's medical condition, the history and probable course of his illness, the degree of pain he is in and/or the nature of his disability at the time when the request for authorisation was made or renewed."*

18. Whereas these "reimbursement" cases mainly concerned the free movement of recipients of services (i.e. patients), the Court has repeatedly stated that authorisation schemes were also barriers to the freedom to provide services from the service provider's point of view.[38] Health care professionals who wish to move to another country and provide medical services there, also enjoy freedom to provide of services within the meaning of Articles 49 and 50 EC Treaty. Despite the fact that it is rather unlikely that a significant number of health professionals will cross borders to perform temporarily medical treatment there,[39] a relevant question remains as to how national health care systems deal with this scenario of cross-border medical service provision.

19. Article 50 EC sets forth the principle of equal treatment which means that health care professionals established in another Member State must comply with the rules of the Host Member State governing access to the profession and its exercise. In order to facilitate the freedom to provide health care services, sectoral Directives for specific medical professions, such as doctor, nurses, dentists, midwives, pharmacists and veterinary surgeons have been adopted from 1975 to 1985. As from 1985, sectoral harmonisation has been replaced by horizontal harmonisation in the context of the New approach towards harmonisation and the recognition of diploma and professional qualifications pertaining to regulated professions has been the subject of several horizontal directives. EU rules on professional recognition have now been consolidated in one horizontal Directive

[37] C-372/04, *Watts*, par 116.
[38] See C-372/04, *Watts*, par 98.
[39] T.K. Hervey and J.V. Mc Hale, Health Law and the European Union, 2004, Cambridge University Press, p.198-9.

2005/36/EC of 7 September 2005, which entered into force on 20 October 2005.[40] Member States wishing to restrict the provision of health care services on their territory by health care professionals established in another Member State are authorized to do so only in the framework of the harmonisation directives.

20. The fundamental mechanism of the new horizontal Directive 2005/36/EC is that Member States may not restrict, for any reasons relating to professional qualifications, the free provision of services in another Member State, where the service provider is legally established in the Home Member State for the purpose of pursuing the same professional activity there, and has done so for at least two years (Article 5). This principle applies whenever the service provider moves to another Member State to pursue his activity there on a temporary and occasional basis. A clear distinction between the (temporary) provision of services and the establishment is however lacking. Whereas the Commission - in its original proposal[41] - clarified that the provision of a service could not exceed 16 weeks per year, the final text of the Directive 2005/36/EC does no longer contain a specific time reference. In accordance with established ECJ case law, it now states that the temporary and occasional character has to be assessed on a case-by-case basis in the light of its duration, its frequency, its regularity and its continuity.[42] For the Court, one cannot determine "*in an abstract manner, the duration or frequency beyond which the supply of a service or of a certain type of service in another Member State"* is no longer a (temporary) provision of services in the sense of Articles 49 and 50 EC but an establishment in the sense of Article 43.[43]

21. In accordance with the established case law of the ECJ, the Host Member State can nonetheless impose certain requirements justified by the public interest on health care professionals who temporarily provide services on its territory. The latter shall be subject to professional rules of a professional, statutory or administrative nature as well as disciplinary rules that apply to health care professionals of the Host Member State (Article 5, par 3). Furthermore, the Host Member State may also impose *"specific requirements due to the application of professional rules justified by the general public interest. Rules of this kind relate, for example, to organisation of the profession, professional standards including those concerning ethics, and supervision and liability"* (Recital 11).

22. Whereas the Host Member State also remains entitled to ask for a prior declaration including a proof of nationality and evidence of professional qualifications (Article 7), foreign health care professionals are exempt from registration with a professional organisation or body although they are often

[40] Deadline for transposition is 20 October 2007.
[41] COM (2002) 119 final.
[42] See C-55/94, *Gebhard*, par 39.
[43] C-215/01, *Schnitzer*, par 31.

submitted to this type of registration in their Home State. Member States may only maintain automatic temporary registration provided that such registration does not delay the provision of service or does not entail any financial burden for the health care professional (Article 6 (a)).

23. Furthermore, it is forbidden for the Host Member State to require from foreign doctors a *"registration with a public social security body for the purpose of setting accounts with an insurer relating to activities pursued for the benefit of insured persons."* (Article 6 (b)). The exact scope of Article 6(b) remains however uncertain especially since the Directive clarifies at the same time that its provisions *"do not affect the powers of the Member States as regards the organisation of their national social security system and determining the activities which must be pursued under that system."* (Recital 38) In some countries, reimbursement is indeed only allowed when the doctor providing treatment is officially registered with the public social security body or concludes an agreement with a health insurance institution.[44]

    With regard to the old Article 18 of the Doctor's Directive 93/16/EEC (corresponding to new Article 6 (b)), the ECJ clarified that it does not seek *"to eliminate all obstacles that might exist in the Member States relating to the reimbursement of the cost of medical services by an insurance body to which the doctor established in another Member State does not belong."*[45] Furthermore, in her opinion delivered on 4 October 2001 in this case, Advocate General Stix-Hackl stated that this provision *"differentiates between insurance bodies and public social security bodies. From this it may be inferred, first, that by public social security bodies, with which there can be no requirement to register, institutions distinct from insurance bodies must be meant. A contrario, this means that registration with an insurance body [such as national health schemes] can in fact be required as a condition for reimbursement of the cost of treatment."* (par 99)

    The Advocate General went on to declare that *"[s]ince the question of the conditions governing payment for medical services in all the Member States is one of the matters most central to national social security schemes, it is difficult to accept that the Community legislature had concealed that question in a diploma recognition directive."* (par 101)

23. The fact that in this case the Court drew a clear distinction between the registration with a public social security body on the one hand and the registration with a health insurance body as a condition for reimbursement of the cost of medical treatment on the other hand, does however not solve the question whether

[44] See also Miek Peeters, "Free Movement of Medical Doctors: The New Directive 2005/36 on the recognition of Professional Qualifications", *European Journal of Health Law* 2005, 384.
[45] C-232/99, *Commission v Spain*, par 52.

Articles 49-50 EC allow Member States to oblige foreign health care professionals providing temporary services only to register or participate in a contracting scheme of a host Member State as a condition for reimbursement of costs of medical treatment in that same State. In this respect, the "reimbursement" cases mentioned earlier clearly reveal that reimbursement for medical care from a foreign health care provider cannot be refused on the basis of the argument that the provider has not concluded an agreement with the insured person's sickness fund of the Member State in which the patient is affiliated and that it constitutes an unjustified barrier to free movement not only for the patient, but also for the service provider.[46]

24. The particular "reimbursement" case of *Müller-Fauré* (C-385/99) also shows that it remains a matter for the Member State in which the patient is affiliated to decide which medical treatments are covered by sickness insurance and to establish the extent to which sickness coverage is made available to its insured patients. The Court indeed concluded that *"it is for the Member States alone to determine the extent of the sickness cover available to insured persons, so that, when the insured go without prior authorisation to a Member State other than that in which their sickness fund is established to receive treatment there, they can claim reimbursement of the cost of the treatment given to them only within the limits of the cover provided by the sickness insurance scheme in the Member State of affiliation."* (par 98) The Court applied the same reasoning to the conditions on which benefits granted, but specified that it was only the case *"... in so far as they are neither discriminatory nor an obstacle to freedom of movement of persons ..."* (par 106).

25. Despite the fact that Member States are indeed entitled to establish the conditions of health care coverage, it cannot be denied that the obligation to comply with Home Member State reimbursement rules (for instance by means of authorisation procedure) remains a restriction to the EC Treaty rules on free movement. In *Commission v France (C-496/01)* - which concerned French rules prohibiting sickness insurance funds from reimbursing the costs of analyses carried out by bio-medical analysis laboratories with their business seats in another Member State without prior authorisation, the Court observed that *"it de facto precludes laboratories established in another Member State from being able to provide services to insured persons established in France. It therefore constitutes a restriction of the freedom to provide services."* It is established case law that the fact that this obligation falls with the scope of free movement means that *"it is necessary, where justification is based on an exception laid down by the Treaty or indeed on an overriding general-interest reason, to ensure that the measures taken in that respect do not exceed what is objectively necessary for that purpose and that the same result cannot be achieved by less restrictive rules."*[47]

[46] See e.g. C-385/99, *Müller-Fauré*, par 44 concerning the Netherlands sickness insurance scheme.
[47] See e.g. C- 385/99, *Müller-Fauré*, par 68 and C-157/99, *Smits and Peerbooms*, par 75.

In the case of bio-medical analysis laboratories, the Court was of the opinion that *"such rules may, in principle, be justified ... in so far as they are designed to contribute to ensuring a high level of public health protection. However, the refusal by sickness insurance funds to reimburse the costs of analyses carried out by laboratories with their place of business in another Member State goes beyond what is objectively necessary for that purpose."* (C-496/01, par 92)

"In the absence of harmonisation measures, Community law ... does not preclude the French Republic from imposing, in the context of an authorisation scheme, its level of public health protection on laboratories established in another Member State which wish to offer services to members of one of the French sickness insurance schemes." (C-496/01, par 93)

Whereas the Court concluded that refusing reimbursement for the costs of analyses carried out by a bio-medical analysis laboratories on the ground that the laboratory was established in another Member State went beyond what was necessary for the protection of public health, it provides Member States nonetheless *"a clear means of restricting, or at least rationalizing, "exodus" from the national welfare system towards other Member States' facilities, through the use of a prior authorization procedure."*[48]

26. In line with the Court's rulings in the "reimbursement" cases, authorization procedures must however *"be based on objective, non-discriminatory criteria which are known in advance ..."*.[49] As long as these criteria are non-discriminatory and consistent, Member States are free to decide what kind of health care they want. However they cannot preclude other health care providers from offering services meeting their quality standards (or refuse to reimburse them for their services) for the sole reason that there is a cross-border element. Furthermore, Member States should take full account measures of harmonisation or mutual recognition at EU level.[50]

27. In the absence of harmonising measures, the ECJ tends to leave a wide margin of discretion to the Member States to establish whether national measures are proportionate to the 'public interest' objectives concerned, such as the protection of public health or the safeguarding of the balance of the social security system.[51] In particular, with regard to the exercise of the medical profession on a Member State's territory, the ECJ recognised for instance that *"the decision of a Member State to restrict to a group of professionals with specific qualifications, such as*

[48] V Hatzopoulos and T U Do, "The case law of the ECJ concerning the free provision of services: 2000-2005, *Common Market Law Review* 2006, p. 941.
[49] See e.g. C-372/04, *Watts*, par 116.
[50] See *a contrario*, C-496/01, *Commission v France*, par 93.
[51] See e.g. Y. Jorens, M. Coucheir and F. Van Overmeiren, Access to Health Care in an Internal Market: Impact for Statutory and Complementary Systems, Ghent University, Department of Social Law, 2005, 27.

qualified doctors, the right to carry out medical diagnoses and prescribe treatments for illness or to alleviate physical or mental disorders may be considered to be a suitable means of achieving the objective of safeguarding public health."[52] Faced with the question whether a Member State could then lawfully prohibit the exercise of a medical activity - in casu the activity of "healers" - by those not being qualified as doctors, the Court concluded that this did *"not go beyond what is necessary to achieve the aim of safeguarding public health"*[53] despite the fact that it could be argued that there was a less restrictive measure than the prohibition of that profession in order to safeguard public health.[54]

C. Freedom of establishment

28. In the event that a self-employed health care provider or a legal person wishes to establish permanently in another EU Member State in order to perform health care services there, Treaty provisions on the freedom of establishment apply. According to Article 43 EC, freedom of establishment means that "restrictions ... on nationals of a Member State in the territory of another Member State shall be prohibited" *and guarantees "*the right to take up and pursue activities as self-employed persons and to set up and manage undertakings ... under the conditions laid down for its own nationals by the law of the country where such establishment is effected." *As for the provision of services, the rule is the one of equal treatment between nationals of the Host Member State and professionals coming from another Member State.*

29. Article 43 EC only applies in case of an "establishment". The Court of Justice qualifies the notion of establishment as "the actual pursuit of an economic activity through a fixed establishment in another Member State through a fixed establishment in another Member State for an indefinite period." *(C- 221/89,* The Queen v Secretary of State for Transport*, par 20). Furthermore, it has clarified the distinction between temporary services and establishment. In order for the freedom of establishment to apply, a service provider needs* "to participate, on a stable and continuous basis, in the economic life of a Member State other than his State of origin and to profit therefrom."[55] *In the* Gebhard *case, the Court listed various criteria to be taken into consideration by the national judge when he must distinguish an establishment from the mere provision of services: the duration of the service, its frequency, its regularity and continuity.*[56]

*However, later on, the Court added that one cannot determine on the basis of the Treaty provisions "*in an abstract manner, the duration or frequency

[52] C-294/00, *Deutsche Paracelsus v Gräbner*, par 43.
[53] C-294/00, *Deutsche Paracelsus v Gräbner*, par 50.
[54] C-294/00, *Deutsche Paracelsus v Gräbner*, par 45.
[55] See e.g. 2/74, *Reyners v Belgium*, par, C-55/94, *Gebhard*, par 25 and C-70/95, *Sodemare*, par 24.
[56] C-55/94, *Gebhard*, par 27.

beyond which the supply of a service or of a certain type of service in another Member State" *is no longer a (temporary) service provision but an establishment.*[57] *Even if a service is provided frequently and during many years, it may still be a service in the sense of Articles 49 and 50 EC and not an establishment. The notion of establishment can nevertheless be considered to include the setting up or running of a clinical laboratory, a pharmacy, a hospital facility or even a private practice of a self-employed health care professional (provided that the presence of a stable and continuous participation in economic life of the host Member State is proven).*

30. The text of Article 43 EC suggests that freedom of establishment solely targets national restrictions that are discriminatory on the basis of nationality. With regard to national measures restricting the access to professions, the Court of Justice has however gradually broadened the application of Article 43 EC to measures that are indistinctly applicable.[58] In doing so, the Court transposed its case law in Cassis de Dijon to the field of establishment as it has been done previously to the field of the freedom to provide services.

31. In *Commission v France* (C-96/85) - concerning a discriminatory provision - the Court held that the *"prohibition on the enrolment in a register of the order in France of any doctor or dental surgeon who is still enrolled or registered in another Member State is too absolute and general in nature to be justified by the need to ensure continuity of medical treatment or of applying French rules of medical ethics in France."* (par 14) The prohibition on enrolment in a register of the French order was clearly discriminatory since it applied only to doctors already enrolled or registered in another Member State.

32. In subsequent case law rendered as of 1993, the Court of Justice expanded the prohibition mentioned in Article 43 and ruled that *"[i]n the absence of harmonisation of a profession, Member States remain, in principle, competent to define the exercise of that profession but must none the less, when exercising their powers in this area, respect the basic freedoms guaranteed by the Treaty."*[59] National measures governing the exercise of medical professions must thus not only be applied in a non-discriminatory way but *"they must be justified by overriding reasons based on the general interest; they must be suitable for securing the attainment of the objective which they pursue; and they must not go beyond what is necessary in order to attain that objective."*[60]

    In line with this reasoning, the Court holds that Member States can rely upon the protection of public health to justify not only discriminatory measures (as stated in

[57] C-215/01, *Schnitzer*, par 31.
[58] See C-19/92, *Krauss* and confirmed afterwards in C-55/94, *Gebhard*.
[59] C-108/96, *Mac Quen*, par 24.
[60] C-108/96, *Mac Quen*, par 26.

Article 46 EC) but also measures that apply indistinctly. Faced with a challenge targeting Belgian national rules reserving the task of carrying out certain optical examinations to a category of professionals holding specific qualifications, such as ophthalmologists, to the exclusion of opticians who are not qualified medical doctors, the Court indeed confirmed that the measure was lawful under Article 43 EC, since it was proportionate to secure the objective of attaining a high level of health protection.[61]

33. Apart from the protection of public health as such, the Court also recognised as possible justification the following related grounds: a concern to ensure that individuals enjoy the most effective and complete health protection possible, the need to ensure continuity of medical treatment, applying French rules of medical ethics in France.[62]

34. The power of the Host Member State to define the exercise of a certain medical profession and to justify restrictions to access to health care professions under Treaty provisions on establishment is however affected by the presence of a framework at EU level on the mutual recognition of professional qualifications. As explained above in the chapter on free movement of services, one horizontal Directive (2005/36/EC) now governs the issue and replaces all existing sectoral directives for specific medical professions, such as doctor, nurses, dentists, midwives, pharmacists and veterinary surgeons and existing horizontal directives for regulated professions. As regards the taking up of the medical professions, the fundamental mechanism of this framework is the automatic recognition on the basis of a minimum harmonisation of training requirements. It implies that Host Member States will have to give an automatic recognition to the diplomas originating from other Member States provided that they correspond to certain minimum training requirements. Furthermore, the framework provides coordinated procedures about required documents and information to facilitate the access to and the pursuit of a profession in another Member State.[63]

35. It is clear that this EU framework substantially reduces the power of Member States to impose restrictions relating to the holding of professional qualifications for medical professions which had been the object of sectoral harmonisation directives. When the healthcare professions concerned were not harmonised by sectoral directives but are subject to the general horizontal directive, the recognition of diploma is not automatic and the Host Member state is still

[61] C-108/96, *Mac Quen*, par 31-38.
[62] C-96/85, *Commission v France*, par 10 and 14: even though they did not manage to justify the national measure at stake.
[63] For an overview of the main features of the new Directive: Miek Peeters, "Free Movement of Medical Doctors: The New Directive 2005/36 on the recognition of Professional Qualifications", *European Journal of Health Law* 2005, 373-396.

authorized to impose a qualification exam or a professional stage. In both cases, Host Member States remain however free to provide regulatory instruments for planning health care supply, personnel standards in health care institutions, price-fixing mechanisms, referral systems, etc... in order to guarantee accessible and reasonably priced health care to every citizen, continuity of care, and patient protection. Whereas one could consider that the obligation to comply with these standards is a restriction to under Article 43 EC, the Court has been hesitant to do so. Whenever a restriction deals with the actual pursuit of a medical profession rather than the access to a medical profession, the restriction must to a certain degree be discriminatory on the basis of nationality in order for the violation of article 43 to apply.[64]

36. With regard to the refusal under the Belgian social security scheme to reimburse services of clinical biology laboratories whose members, partners or directors are not all natural persons authorised to carry out medical analyses, the Court stated that *"each Member State is ... free to lay down rules for its own territory governing the activities of laboratories providing clinical biology services."*[65] The Court concluded that the refusal was not an infringement of Article 43 EC (formerly Article 52 EC) since *"the Belgian law does not prevent doctors or pharmacists who are nationals of other Member States from establishing themselves in Belgium and operating there a laboratory to carry out clinical analyses qualifying for reimbursement under the social security system."*[66]

[N.B. On 18 July 2002, the European Commission sent a formal request to Belgium to modify certain provisions of Royal Decree no 143 of 30 December 1982 (laying down conditions in relation to clinical analysis) because it considered that Belgium imposed too restrictive conditions upon medical laboratories in order to qualify for reimbursement by the sickness insurance scheme. Apart from the requirement that clinical laboratories had to be run by doctors, pharmacists or chemical science graduates, these conditions also included: a ban for operators to operate more than one laboratory within a specific radius and a ban preventing operators to have links with another entities active in the medical profession. Belgium subsequently modified its national legislation.]

37. In the *Sodemare* case (C-70/95) - which concerned the Italian rules reserving the participation in the social welfare system to non-profit making economic operators - the Court even seemed to avoid all together the question whether the national measure was a restriction in the sense of Article 43 EC. After having stated *"a Member State may, in the exercise of the powers it retains to organize its social security system, consider that a social welfare system of the kind at issue in this case necessarily implies, with a view to attaining its objectives, that the admission*

[64] T.K. Hervey and J.V. Mc Hale, Health Law and the European Union, 2004, p. 201.
[65] Case 221/85, *Commission v Belgium*, par 9.
[66] Case 221/85, *Commission v Belgium*, par 11.

of private operators to that system as providers of social welfare services is to be made subject to the condition that they are non-profit-making" (par 32), the Court concludes that national measure does not represent any discrimination on the basis of nationality or place of establishment. (see par 33: *"the fact that it is impossible for profit-making companies automatically to participate in the running of a statutory social welfare system of a Member State by concluding a contract which entitles them to be reimbursed by the public authorities for the costs of providing social welfare services of a health-care nature is not liable to place profit-making companies from other Member States in a less favourable factual or legal situation than profit-making companies from the Member State in which they are established."*)

38. The extent to which EC provisions on freedom of establishment could interfere with national rules governing the organisation of health care on its territory is demonstrated by a series of infringement procedures launched by the Commission on 28 June 2006 against Italy, Austria and Spain with regard to national restrictions relating to the opening and running of pharmacies. The Commission alleges the incompatibility of the following measures with the freedom of establishment (in conjunction with the freedom of movement of capital):

    - Italian rules establishing a ban on the acquisition of holdings by enterprises active in the distribution of medicines (or having links with companies active in this area) in private pharmaceutical companies or community pharmacies as well as rules reserving the ownership of pharmacies for pharmacists or legal entities consisting of pharmacists.
    - Spanish rules on territorial planning, criteria applied in the administrative licensing procedures and on the ownership of pharmacies.
    - Austrian rules: discrimination on the basis of nationality for the purposes of obtaining a licence to operate a pharmacy; a ban on opening a pharmacy in areas without a doctor's surgery; limitations on the number of pharmacies according to the number of inhabitants and the minimum distance between pharmacies; limitation of the choice of legal form for a pharmacy and a ban on operating more than one pharmacy.

D. Free movement of goods

39. Given the fact that medical devices, medicines and other pharmaceutical products clearly are products that can be valued in money and form the subject of commercial transactions, they fall within the scope of EC Treaty provisions on the free movement of goods (Article 28-31 EC).[67] Free movement of goods implies that Member States shall refrain from taking national measures for the procurement or marketing of "medical" goods that are discriminatory on the basis of nationality as well as from applying any quantitative restriction to imports or exports of goods or any measure having equivalent effect. According to the European Court of Justice, measures having equivalent effect cover *"[a]ll trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade."*[68] Whether or not a certain national measure falls within the scope of free movement of goods depends on its effect, actual or potential, on intra-Community trade, which means that the said measure does not necessarily have to intend to regulate trade between Member states. Given this broad interpretation, free movement of goods potentially applies to a broad range of national rules in the field of health care.

40. In the leading case Cassis de Dijon, rendered in 1979 (Case 120/78) and which led to the new approach in the field of harmonisation, the Court applied the prohibition of Article 28 to indistinctively applicable measures of the Host Member State unless they are justified by mandatory requirements. The protection of public health is one of the mandatory requirements admitted by the Court since Cassis de Dijon.[69] Following this case law the concept of measures having an equivalent effect to quantitative restrictions to the importation of goods received an ever wide interpretation in the subsequent decisions of the Court.

41. However, in 1993 the Court reversed its case law and recognised that certain rules on selling arrangements fall outside the scope of the free movement of goods *"so long as those provisions apply to all relevant traders operating within the national territory and so long as they affect in the same manner, in law and in fact, the marketing of domestic products and of those from other Member States."*[70] This means that national rules restricting the sale of certain goods, such as dangerous goods or pharmaceuticals, probably fall outside the scope of the EC rules on free movement of goods.[71]

[67] For a definition of goods within the meaning of the EC Treaty, see C-7/68, *Commission vs Italy*, p. 429; it should be noted however that the same definition applies to services, see C-97/98, *Jägerskiöld and Gustafsson*.
[68] Case 8/74, *Dassonville*, par 5.
[69] Case 120/78, *Rewe-Zentral v Bundesmonopolverwaltung für Branntwein*, par 8.
[70] C-267/91 and 268/91, *Keck and Mithouard*, par 16, see also e.g. C-322/01, *DocMorris*, par 68.
[71] T.K. Hervey and J.V. Mc Hale, Health Law and the European Union, 2004, Cambridge University Press, p. 47 and K.J.M. Mortelmans, "De interne markt en de gezondheidsexcepties", *SEW* 2005 p. 405.

42. When the national rules fall within article 28 EC Treaty, the free movement of goods is first of all limited by the EC Treaty itself. According to Article 30 EC, national prohibitions or restrictions on imports, exports and goods in transit are justified on several 'public interest' grounds, such as *"the protection of health and life of humans, animals or plants"*. Member States have invoked this particular ground to justify national measures dealing with public health concerns. Whereas many cases before the ECJ involved measures dealing with health risks related to food, the use of dangerous products or measures promoting road safety, other cases directly dealt with measures relating to goods in the medical sphere. It concerned e.g.:
    - national rules establishing a monopoly for the importing, the marketing and the distribution of a pharmaceutical product;[72]
    - a national monitoring procedure and charging fees for the import of pharmaceutical products;[73]
    - a national system regulating prices for imported medicines;[74]
    - national rules prohibiting pharmacists from substituting a therapeutically equivalent medicinal product for that prescribed by the doctor;[75]
    - a national prior authorisation scheme for the reimbursement of the purchase of spectacles;[76]
    - a national prohibition of advertising for foreign medicinal products which are not authorised in importing state but which can be imported under certain conditions;[77]
    - a national system providing a compulsory registration procedure applicable to all reagents as well as the obligation to state the registration number on the external packaging and the notice accompanying each reagent;[78]
    - national restrictions to internet sales of medicinal products for human use by pharmacies established in another Member State;[79]
    - a prior authorisation procedure for personal imports of medicinal products.[80]

43. Apart from the protection of human health, health care and pharmaceutical policy measures can also be justified by mandatory requirements admitted by the Court, such as the safeguarding of the financial balance of national social security schemes.[81] The recognition of these 'public interest' grounds does not necessarily

[72] Case 104/75, *De Peijper*, C-369/88, *Delattre* and C-60/89, *Monteil and Samanni*.
[73] Case 32/80, *Kortmann*.
[74] Case 181/82, *Roussel*.
[75] Case 266&267/87, *Royal Pharmaceutical Society of Great-Britain*.
[76] C-120/95, *Decker*.
[77] C-320/93, *Ortscheit*.
[78] C-55/99, *Commission v France (Medical Reagents)*.
[79] C-322/01, *DocMorris*.
[80] C-212/03, *Commission v France*.
[81] C-120/95, *Decker*, par 39.

mean that the said national measures are justified in the light of Community law. The core of the conformity test with EC Treaty rules lies in the tests whether the national measure at stake is strictly justified by and proportional to the 'public interest' ground.

44. With regard to the safeguarding of the financial balance of national social security schemes, the ECJ considered in the *Decker* case that *"reimbursement at a flat rate of the cost of spectacles and corrective lenses purchased in other Member States has no effect on the financing or balance of the social security system*"[82] in order to conclude that a prior authorisation scheme for the purchase of any medical product abroad was not justified under the EC Treaty rules.

45. With regard to the justification in Article 30 EC - including protection of human health - the Treaty stipulates that national prohibitions or restrictions may not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. In this respect, the ECJ has clarified that *"... the principle of proportionality which underlies the last sentence of Article 36 of the EC Treaty [now, after amendment, Article 30 EC] requires that the power of the Member States to impose restrictions in trade in products from other Member States should be limited to what is necessary to attain the objectives of protection being legitimately pursued..."*[83]

"It is settled case-law that a national provision which has, or is likely to have, a restrictive effect on the importation of products is compatible with the Treaty only to the extent that it is necessary for the effective protection of the health and life of humans. A national provision cannot therefore benefit from the derogation in Article 36 of the Treaty if the health and life of humans may be protected just as effectively by measures which are less restrictive of intra-Community trade ..."[84]

46. It follows from this that Member States need to prove that a particular national measure actually serves the protection of human health and that human health can only be effectively protected by the said measure which is the least restrictive measure available regarding its effect on trade between Member States. In order to prove that specific national rules are necessary to give effective protection to human health means that the Member State concerned will have to provide a detailed assessment of the alleged risk resulting from the possible marketing of the goods. In *Commission v Netherlands* (C-41/02) - which concerned the Netherlands administrative practice making the marketing of certain foodstuffs from other Member States subject to proof of a nutritional need in the Netherlands population - the European Court of Justice developed this argument by stating that

[82] C-120/95, *Decker*, par 40.
[83] C-55/99, *Commission v France*, par 29.
[84] C-55/99, *Commission v France*, par 42.

"[I]n a number of cases, the assessment [...] will demonstrate that there is much uncertainty, in science and in practice, in that regard. Such uncertainty, which is inseparable from the precautionary principle, affects the scope of the Member State's discretion and thus also the manner in which the precautionary principle is applied." (par 51)

"A proper application of the precautionary principle requires, in the first place, the identification of the potentially negative consequences for health of the proposed addition of nutrients, and, secondly, a comprehensive assessment of the risk for health based on the most reliable scientific data available and the most recent results of international research." (par 53)

"Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures." (par 54)

47. The discretion of Member States relating to the protection of human health is particularly wide not only where uncertainty in scientific research as to the concerned goods exists but also where specific EU rules harmonising provisions of public health protection lack. In the *Tedeschi* case, the Court stated that *"... [w]here ... Community directives provide for the harmonisation of the measures necessary to ensure the protection of animal and human health and establish Community procedures to check that they are observed, recourse to Article 36 [currently Article 30 EC] is no longer justified and the appropriate checks must be carried out and the measures of protection adopted within the framework outlined by the harmonizing directive."*[85]

    In the *DocMorris* case (C-322/01) for instance, the Court was of the opinion that the German general prohibition of importing medicinal products which had not obtained the prior market authorisation corresponded to the prohibition at Community level on placing on the market medicinal products which have not been authorised in the Member State concerned as it was laid down by a specific Community measure. The Court concluded that the said national rule could not be characterised as a measure having equivalent effect to a quantitative restriction on imports within the meaning of Article 28 EC. Consequently, Article 28 tot 30 EC could not be relied upon to circumvent the system of national authorisation provided by that specific Community measure.[86]

48. However, reliance upon Article 28 and 30 EC is not automatically prohibited in case of harmonising measures at EU level. It follows from the *DocMorris* case

[85] Case 5/77, *Tedeschi*, par 35.
[86] C-322/01, *Doc Morris*, par. 52-53.

that a Community measure that governs a specific matter becomes the only framework of judicial review provided that it deals with the matter exhaustively. In this case, the 'harmonising' measure replaces the Treaty as the framework of judicial review. But if a particular matter has not been exhaustively dealt with at EU level, Member States remain entitled to derogate from the principle of free movement of goods by relying upon by Articles 28-30 EC.[87]

Consequently, the power of Member States to adopt a specific national measure relating to human health protection directly depends on the detailed character of EU harmonisation in the field in which Member States intend to take a specific measure. Both in the field of medicines and medical devices, harmonised EU rules have been put into place. Whereas these rules often provide an exhaustive regulatory solution (so called "old style" harmonisation), other rules only determine a set of minimum standards which are necessary to protect health interests, leave Member States' the freedom to set higher standards for home producers or suppliers of medical goods, but oblige them to admit on their internal market products manufactured in conformity with the standards of other Member States provided that the latter comply with EU minimum standards (so called "new approach" harmonisation).[88]

49. As regards medicines for instance, a specific Community legislative framework on the authorisation, marketing and free movement of pharmaceuticals applies. As from 18 December 2001, all the existing Directives were repealed and replaced by Directive 2001/83 of 6 November 2001 on the Community Code relating to medicinal products for human use.[89] The "Community Code relating to medicinal products" now contains all existing provisions on production, marketing, distribution and utilization of medicinal products. The fundamental principle of the Community framework is that no medicinal product can be marketed unless an authorisation has been issued by a competent authority. Whereas the Community Code strictly regulates the requirements relating to marketing authorisation requests, the decision to approve or refuse new medicinal products is in principle a matter for national authorities. The Community legislator nonetheless introduced a specific procedure for the approval of products in one Member State that have already been approved in another Member State (the so called 'mutual recognition' procedure). On this basis, Member States have to recognise an authorisation issued by another Member State, unless they succeed in proving that the said medicinal product presents a potential serious risk to public health. In the event of a disagreement between Member States about this risk, an arbitration before the European Medicines Evaluation Agency (EMEA) must take place.

[87] See C-322/01, *DocMorris*, par 64.
[88] For further explanation of the distinction, see T.K. Hervey and J.V. Mc Hale, Health Law and the European Union, 2004, Cambridge University Press, p. 48-59.
[89] OJ 2001, L 311, p. 67.

Whereas the process of harmonisation of authorization procedures originally focussed on this mutual recognition procedure, the Community legislator added from 1993 onwards a more 'centralised' authorisation procedure, administered by the European Medicines Evaluation Agency (EMEA). If a manufacturer chooses to use this community authorization procedure, its medicines are authorized to freely circulate within the Community. This procedure is also compulsory for the approval of specific medicinal products, such as new biotechnological products and certain other innovative medicinal products.[90]

50. Through the adoption of three specific European Directives in the nineties, a specific legal framework was also put into place at EU level in order to deal with the free movement of medical devices. They concern active implantable medical services, medical services in general and in vitro diagnostic medical services (see Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC). This legal framework sets out the essential requirements for medical devices before being placed on the market or being put into service. These requirements relate to risk assessment and risk management, chemical, physical and biological properties, infection and microbiological contamination, construction and environmental properties, protection against radiation, information supplied by the manufacturer etc. Products can only be put on the market or put into service after a risk assessment, a risk management process and a risk/benefit analysis. The Directives also provide voluntary harmonized European standards as well as conformity assessment procedures to assist Member States in verifying compliance the said essential requirements. Medical devices fulfilling the essential requirements and having undergone these conformity assessment procedures will bear the CE marking of conformity. At the same time these Directives provide specific mechanisms available to national competent authorities to intervene on the market ("safeguard clause") when certain products constitute a danger for public health for patients, users of third parties.

51. The objective of these Directives is to remove technical barriers to the marketing and free movement of these medical goods. Even though these Directives have a certain influence on national health care and pharmaceutical policy, Member States retain nonetheless national competence for the organisation of health care on their territory and particularly for matters such as health infrastructures, content of medical care, the conditions concerning the right or duty to be insured with a social security scheme, the management of public health funding and sickness insurance schemes and the reimbursement of costs of health care received in their territory. In the absence of EU harmonisation on these points, measures adopted by Member States in these matters which may affect the marketing of medical products and indirectly influence the possibilities of importing those products will

[90] For an overview of the latest changes to the Community Code, see J.L. Valverde and P. Weissenberg, "The Challenges of the new EU Pharmaceutical Legislation", *Pharmaceuticals Policy and Law, 2005, Vol 6.*

have to be evaluated in the light of the Treaty rules on the free movement of goods.[91]

52. The category of measures adopted by Member States which may affect the marketing of a product is not limited to measures which create a complete barrier to the marketing of a medicinal product. In *Commission v Belgium* (C-38/03) for instance, the Belgian government had laid down technical criteria to be met by wheelchairs as well as a series of more general criteria which the economic operator of wheelchairs in order to be eligible for reimbursement by social security. Wheelchairs bearing EC markings that did not fulfil the said requirements were excluded from the list of wheelchairs reimbursable under Belgian social security. According the Court of Justice, these measures clearly fall within the scope of the EC rules on free movement of goods since they affected the marketing of wheelchairs on Belgian territory.[92] Since Belgium did not produce any argument to show that its restriction to the free movement of goods was justified by a 'public interest' ground listed (or not) in Article 30 EC, the Court concluded that it had failed to fulfil its obligations under Article 28 EC.

53. Other measures adopted by Member States falling within the free movement of goods may only indirectly affect the marketing possibilities of certain medical products. They include measures restricting the amount of entities in which certain medical goods can be installed and used. In a recent infringement procedure launched against Belgium for instance, the European Commission argued that, by restricting the amount of nuclear medicine services in which a PET scanner can be installed, Belgium has failed to fulfil its obligations under Article 28 EC. The Belgian law of 27 April 2005 on the management of health care budget and relating to several health care provisions[93] provides a series of criteria applicable to nuclear medicine services in which a PET scanner can be installed. On the basis of the application of these criteria, a maximum of 13 nuclear medicine services have received permission to install and use a PET scan. By a decision of 12 October 2006, the Commission invited Belgium to submit its observations on the alleged infringement.

E. Competition rules

54. It should be noted, as a preliminary remark, that even if it appears desirable to adopt the same solution in the field of the freedom to provide services (see above) and in that of competition, since those provisions seek to attain the completion of

[91] See e.g. 238/82, *Duphar and others*; C-120/95, *Decker*, par 22 and 24 and C-38/03, *Commission v Belgium*, par 14.
[92] C-38/03, *Commission v Belgium*, par 17.
[93] Published in Belgian Official Gazette, 20 May 2005.

the internal market, the scope of the freedom to provide services and that of competition and their conditions of application are, however, not identical. To this extent, there is nothing to prevent a transaction involving an exchange being classified as a provision of services, even where the parties to this exchange are not undertakings for the purposes of competition.

Indeed Member States may withdraw certain activities from the field of competition if they organise them in such a way that the principle of solidarity is predominant, with the result that competition law will not apply. On the contrary, the way in which an activity is organised at the national level has no bearing on the application of the principle of the freedom to provide services as long as the condition of remuneration is fulfilled. Thus, although there is no doubt that the provision of health care for retribution is an economic activity for the purposes of Article 49 EC, it does not necessarily entail that the organisations which carry on that activity are subject to competition law.

1. <u>The notion of undertaking and the exercise of an "economic activity"</u>

55. In order for an entity to be subject to competition law, it must be classified as an undertaking. Although the EC Treaty frequently refers to the concept, it does not define it and it has been clarified by the case-law, which gave it a functional content. It is established case-law that an entity engaged in an economic activity is an undertaking for the purposes of competition law, irrespective of its legal status and the way in which it is financed.

While it is common ground that certain tasks are not economic by nature (protection of environment or maintenance an improvement of air navigation safety, for instance), this is not necessarily the case with all activities that are linked to the national social security system. In order to determine whether these activities may be classified as economic or non-economic, the European Court of Justice analyses on a case-by-case basis whether the principle of solidarity leads to the exclusion of competition law.

Competition law will apply to the health sector only in so far as solidarity does not predominate therein. In order to determine the degree of solidarity involved, the Court has adopted, in its judgements, a range of tests described hereafter. In doing so, the Court has, given some interesting details regarding those economic activities which will entail the qualification of "undertaking" in the sense of competition law, and those non economic activities defined by predominant social characteristics.

56. The *Poucet* and *Pistre*[94] cases concerned the compatibility with competition law of compulsory membership to a social security scheme. Since there was no particular activity at issue in this case, the Court referred to the nature of the organisations concerned and concluded that *"the concept of undertaking within the meaning of Articles 85 and 86 [now, after amendment, Articles 81 and 82] of the Treaty does not encompass organisations charged with the management of social security schemes of the kind referred in the judgements of the national court"*. In order to reach that conclusion, and without indicating the degree of importance given to each element separately, the Court noted that *"those schemes pursue a social objective and embody the principle of solidarity"*. One might conclude that organisations which fulfil a "purely social purpose", such as a social security fund, do not exercise an economic activity and, therefore, cannot be qualified as undertakings.

57. In its decision of 22 January 2002 in the *Cisal* case[95], the Court concluded that INAIL (the Italian national institute for insurance against accidents at work) fulfilled a purely social purpose in the sense of the *Poucet-Pistre* case law, taking into consideration the following elements: the lack of proportionality between the contributions and the risk insured, between the services provided and the members' incomes, the lack of a direct link between the contributions and services. Thus, INAIL operated in accordance with the principle of solidarity. Moreover, it was subject to the control of the State which set the level of contributions and determined that membership was compulsory. The Court therefore held that INAIL did not carry on an economic activity, with the result that competition law did not apply.

58. In other cases, the Court reached the conclusion that the activity in question was an economic activity.

    In the *FFSA* case,[96] the issue related to the monopoly of management of an old-age insurance scheme conferred to a mutual fund. The Court concluded that the fund managing the supplementary and optional retirement scheme was an undertaking. It emphasised the fact that membership to the retirement scheme was optional, that the scheme was managed in accordance with the principle of capitalisation and that benefits were calculated on the basis of the contributions made. Competition with life-insurance undertakings was present. Notwithstanding the existence of some elements of solidarity, they did not modify the conclusion that the bodies were undertakings.

    In other words, the Court gave four criteria to distinguish a purely social activity from an economic one: (i) the existence of elements of social solidarity; (ii) the functioning of the system on the basis of the principle of distribution or

[94] C-159 and C-160/91, judgment of 17 February 1993.
[95] C-218/00, judgment of 22 January 2002.
[96] C-244/94, judgment of 16 November 1995.

capitalisation; (iii) whether the balance of the system requires or not compulsory affiliation; (iv) whether or not the body or the fund is in competition with other service providers.

59. The Court applied those principles in its subsequent case law. In its judgments of 21 September 1999[97], the Court considered that a Netherlands sectoral pension fund had to be considered as an undertaking. The Court referred to several factors, namely the fact that the membership of the fund was optional, the fact that the fund was managed in accordance with the principle of capitalisation and the fact that benefits were proportional to contributions. The Court also insisted on the existence of competition towards insurance companies. The pursuit of a social objective, the fact that the fund was non-profit-making, the requirement of solidarity and the statutory restrictions applicable were not sufficient to deprive the activity of its economic nature. Indeed, the solidarity established by the fund was limited since only the members could benefit therefrom.

60. A similar reasoning was adopted in *Pavlov*.[98] The Court concluded that the pension fund designed for medical specialists in Netherlands was an undertaking, considering the fact that the fund operated on the basis of the principle of capitalisation and exercised an activity in competition with insurance companies. The absence of any profit-making objective and the requirement of solidarity imposed to the fund did not affect the conclusion that it was an undertaking.

61. Reference should also be made to the *AOK* case.[99] The issue in that case was not the membership to a retirement scheme or a fund but the setting by sickness funds in Germany of maximum amounts to be paid for medicinal products. The Court did not consider the funds to be undertakings because of the manner in which the State had implemented the concept of solidarity. In this case, the nature of competition in the health insurance sector meant that market conditions could not be created. Nevertheless, it should be noted that, in paragraph 58 of the judgement, the Court expressly left open the possibility of the organisations in question to be considered as undertakings in case "*they engage in operations which have a purpose that is not social*".

62. Finally, the Court of First Instance (hereafter, "CFI") ruled on an act of purchase in its *Fenin* decision of 4 March 2003 (case T-319/99). In this case, an association regrouping companies selling sanitary products for hospitals invoked that the

[97] C-67/96, *Albany International*; case C-115 to 117/97, *Brentjens' Handelsonderneming* ; C-119/97, MDB BV.
[98] C-180 to 184/98, judgment of 12 September 2000.
[99] Joined Cases C-264/01, C-306/01, C-354/01 and C-355/01, judgment of 16 March 2004, see also hereafter.

excessive and discriminatory delays in payment upheld by the national Spanish health system (hereafter "SNS") constituted an abuse of dominant position. The Commission, on the basis of the *Poucet* case-law, had considered that these organisations were not undertakings and had, therefore, rejected the complaint.

The association nevertheless disputed this analysis on the ground that the activity in question was an economic one since it concerned an act of purchase. This argument did not convince the CFI which concluded that the purchase activity was not to be considered in itself but only in relation with the subsequent use of the product. In other words, the subsequent use of the product determined the qualification of the purchase activity.

As a result, *« an organisation which purchases goods ─ even in great quantity ─ not for the purpose of offering goods and services as part of an economic activity, but in order to use them in the context of a different activity, such as one of a purely social nature, does not act as an undertaking simply because it is a purchaser in a given market » (par 37).*

If purchasing entities fulfilled an exclusively social purpose in the management of the SNS, they did not act as undertakings in the sense of competition law and were therefore not concerned by the prohibitions of Articles 81 and 82 EC when they purchased goods and equipments. The impact on the market of the activity did not question the fact that the purchasing entity was not necessarily an undertaking in the sense of competition law. The conclusion is consistent with the economic theory according to which the existence of a monopoly does not pose a serious threat to competition since it does not necessarily have any effect on the downstream market. Furthermore, an undertaking in a monopolistic position has no interest in exercising such a pressure on its suppliers that they would be obliged to leave the upstream market.

63. In its judgment of 11 July 2006 (case C-205/03) rendered on appeal, the Court confirmed the CFI had rightly stated that it is the activity consisting in offering goods and services on a given market that is the characteristic feature of an economic activity. As a result, the CFI could rightly conclude that there was no need to dissociate the activity of purchasing goods from their subsequent use in order to determine the nature of that purchasing activity, and that the nature of the purchasing activity must be determined according to whether or not the subsequent use of the purchased goods amounts to an economic activity. It followed that the purchasing activity of the SNS management bodies did not constitute an economic activity in itself, dissociable from the service subsequently provided. The same reasoning can be transposed to services.

64. The *Fenin* case is remarkable since it underlines the distinction to be made between the field of application of the freedom to provide services and the one of

competition rules. Although this case involves the health sector, it can nonetheless be distinguished from the cases referred to here above. While the SNS manages the health insurance system in Spain, it is also responsible for providing health care services to its members. If the relationships of the recipients of the health care with the organisation in charge of the national health system were at issue, it would have been appropriate to rely on the criteria for assessing the degree of solidarity of the system (as developed by the Court since *Poucet* and *Pistre* case-law). However, the questions raised in that case were different, since they involved the economic nature of the provision of free health care services by SNS to its members and of the purchase of medical products from its suppliers.[100]

65. According to Advocate General Poiares Maduro in the *Fenin* case, the activity of providing health care to its members carried on by the SNS did not appear to be of a different kind from the one which was carried on by public hospitals in *Smits* and *Peerbooms*.[101] While it did not only comprise hospital care, it nonetheless included such care. Similarly, if patients did not pay the medical practitioners, those practitioners were nevertheless remunerated. But, in order to determine whether that activity would be subject to competition law, it is necessary to establish whether the State intended to exclude it from all market considerations (in favour of considerations of solidarity).

    Applying those principles to the case in question, the Advocate General noted that if SNS was obliged to guarantee universal cover to all its members free of charge, the CFI did not precise whether the requirements of the market were entirely satisfied by public bodies or whether private organisations having the characteristics of undertakings took part therein as well. As a result, the information available to decide whether or not the activity of providing health care of the SNS is of a non-economic nature was therefore not sufficient.

    In the Advocate General‘s opinion, the case had to be referred back to the CFI in order to determine whether public and private health sectors coexist in Spain or whether the solidarity which exists in the provision of free health care is predominant.

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[100] As the Advocate General Poiares Maduro noted, where it is a question of measuring the degree of solidarity involved in the provision of a service, the relevant parameters are different: " *A guarantee of universal access to users, whether in the field of health, telecommunications or energy, implies solidarity in so far as any differences in actual costs are eliminated in favour of a uniform price. Nevertheless, the constraints imposed by universality of access are not, by themselves, capable of rendering the activity concerned non-economic in nature. A higher level of solidarity is achieved where the service in question is available free of charge, as there is then no connection between the cost of providing the service and the price paid by the user. One final factor is decisive in determining that a sector does not operate under market conditions If public and private entities provide the same services, any analysis will have to be undertaken within the framework of Article 86(2) EC By contrast, if health care services may be delivered only by bodies controlled by the State which are obliged to treat all patients coming to them free of charge, there can be no question of market forces being involved, and the activity will then be guided solely by the principle of solidarity*" (par. 31)

[101] C-157/99, judgment of 12 July 2001.

The Advocate General finally indicated that "i*n any event, were it to be concluded that the SNS carries on an economic activity, that would not call into question the social objectives pursued by the SNS, because such a conclusion does not preclude the implementation of the principle of solidarity, whether in relation to the method of financing by social security and other State contributions or in relation to the provision of services provided to members free of charge on the basis of universal cover. The application of competition law and a recognition that certain sectors must be subject to special rules are not mutually incompatible. On the contrary, the purpose of Article 86(2) EC is precisely to provide a basis for conferring exclusive rights on undertakings entrusted with the operation of services of general interest. The likely effects of making certain activities carried on by undertakings entrusted with the operation of services of general interest subject to competition law do not lead to a reduction in social protection any more than do those which arise from the application of the principle of freedom of movement to the health sector. In both cases, Community law seeks to incorporate principles of openness and transparency into health systems originally conceived on a national scale*" (par. 55).

66. Finally, one should note that the above developments are not, in any case, applicable to Belgian hospitals which, as far as we know, do not offer free of charge services.

2. <u>The application of competition rules</u>

67. Within the essential mechanisms for the organisation of medical care, some are not neutral with regard to competition rules.

A. <u>Price fixing</u>

68. In its judgment of 16 March 2004 in the *AOK* case[102] relating to an objection emanating from certain pharmaceutical companies on the fixed maximum amounts set by sickness funds and applicable to the reimbursement of certain medicinal products, the Court ruled that:

> *« However, as is apparent from the documents before the Court, when the fund associations determine the fixed maximum amounts they merely perform an obligation which is imposed upon them by Paragraph 35 of SGB V in order to ensure continuance of operation of the German social security system. That paragraph also lays down in detail the applicable procedure for determining*

[102] Joined Cases C-264/01, C-306/01, C-354/01 and C-355/01.

the amounts and specifies that the fund associations must observe certain requirements as to quality and profitability. SGB V also provides that if the fund associations do not succeed in determining fixed maximum amounts, the competent minister must then decide them.

It follows that, in determining those fixed maximum amounts, the fund associations do not pursue a specific interest separable from the exclusively social objective of the sickness funds. On the contrary, in making such a determination, the fund associations perform an obligation which is integrally connected with the activity of the sickness funds within the framework of the German statutory health insurance scheme ». (par 61 and following).

In other words, when some groups of those sickness funds fix, pursuant to an obligation imposed upon them by the legislator, maximum amounts corresponding to the upper limit of the price of medicinal products whose cost is borne by sickness funds, they do not act as undertakings or associations of undertakings within the meaning of Article 81 EC, inasmuch as they do not pursue a specific interest separable from the exclusively social objective of the funds, but perform an obligation which is integrally connected with the activity of the funds within the framework of the statutory health insurance scheme.

69. One must however note that in this case Advocate General Jacobs had come to a different conclusion. According to him, the fact that the medical funds were in competition on the contribution rates, for those individuals not submitted to compulsory affiliation, for the management and organisation of services, made the balance weigh more heavily in favour of the qualification of an economic activity. It resulted therefrom that decisions setting fixed amounts were in principle caught by Article 81(1) EC and the liability of the sickness funds would thus depend on whether they were able either to claim the benefit of the State action defence or to justify their decisions pursuant to Article 86(2) EC.

Indeed, if the appellants acted autonomously in setting fixed amounts in breach of Article 81(1) and therefore could not invoke the State action defence, the possibility of defending their conduct under Article 86(2) EC remained. In order to do so, the appellants would first need to show that they had been entrusted with the operation of a service of general economic interest. There was no doubt in the Advocate General's mind that German sickness funds were entrusted with such a service (the provision of a solidarity-based system of statutory health insurance). Secondly, the appellants would need to show that the setting of fixed amounts is necessary in order to allow them to perform correctly their task of general interest. As it resulted clearly from the case-law, the burden of proof would not extend to the demonstration that their task would be impossible if they were unable to set fixed amounts. It would be sufficient to demonstrate that their task could not be performed in economically acceptable conditions or in conditions of financial stability.

The main difficulty regarding the application of Article 86(2) arose in relation to the proportionality of the system of fixed amounts. Given the wide margin of discretion which the national authorities enjoyed, the Advocate General considered that the application of Article 86(2) would be precluded only if the setting of fixed amounts as a method of controlling the cost of medicinal products to the sickness funds would be out of proportion with the objectives. However this was not the case in the opinion of the Advocate General. The German system of setting fixed amounts was a significantly less restrictive method for controlling expenditure on pharmaceuticals than some mechanisms adopted by other States.

B. The accreditation of Medical Practitioners

70. This could fall within the prerogatives of the public authority and in that way escape from the rules of competition.

In this regard, a parallel could be drawn with the *Bodson* case of 4 May 1988 (case 30/87), in which the Court specified that Article 81 EC*" does not apply to contracts for concessions concluded between communes acting in their capacity as public authorities and undertakings entrusted with the operation of a public service."* (par. 18)

C. Promotion of coordination and cooperation of healthcare services

71. In the *Albany* case,[103] the question was raised whether the joint request by employees and workers associations, to make it mandatory to be affiliated to a pension fund, would constitute "an agreement" within the meaning of Article 81 EC which would increasingly reduce competition since it intended to delegate the management of the mandatory pension fund to one single body.

The Court rejected the qualification of agreement on the ground that the agreement at issue was concluded in the form of a collective agreement and was the outcome of collective negotiations between organisations representing employers and workers. As far as its purpose was concerned, that agreement established, in a given sector, a supplementary pension scheme managed by a pension fund to which affiliation was to be made compulsory. The objective of the scheme was to guarantee a certain level of pension for all workers in the sector and therefore contributed directly to improving one of their working conditions, namely their remuneration.

The Court concluded:

[103] C-67/96, *Albany International*.

"It is beyond question that certain restrictions of competition are inherent in collective agreements between organisations representing employers and workers. However, the social policy objectives pursued by such agreements would be seriously undermined if management and labour were subject to Article 85(1) of the Treaty when seeking jointly to adopt measures to improve conditions of work and employment.

It therefore follows from an interpretation of the provisions of the Treaty as a whole which is both effective and consistent that agreements concluded in the context of collective negotiations between management and labour in pursuit of such objectives must, by virtue of their nature and purpose, be regarded as falling outside the scope of Article 85(1) of the Treaty." (Par 59 and 60)[104]

D. The rule of reason

72. Article 81 EC expressly provides, in its third paragraph, the possibility of exempting agreements that restrict competition when they satisfy a number of conditions, in particular when they are indispensable to the attainment of certain objectives and do not afford undertakings the possibility of eliminating competition in respect of a substantial part of the products or services in question. Theoretically, it is only in the precise framework of Article 81(3) EC that the pro and anti-competitive aspects of a restriction may be weighed.

73. However, in a number of judgments the Court and the CFI have favoured a more flexible interpretation of the prohibition laid down in Article 81(1) EC. It results from the case-law that both Courts have, on many

[104] Attention should be paid to the proposition of the Advocate General Jacobs who defended three conditions for ipso facto immunity (par. 191 and following). First, the agreement must be made within the formal framework of collective bargaining between both sides of industry. Secondly, the agreement should be concluded in good faith. In that context account must be taken of agreements which apparently deal with core subjects of collective bargaining such as working time but which merely function as cover for a serious restriction of competition between employers on their product markets. In those exceptional cases, competition authorities should be able to examine the agreement in question. Thirdly, it is necessary to delimit the scope of the collective bargaining immunity, so that the immunity extends only to those agreements for which it is truly justified. The Advocate General suggested as a possible criterion that the collective agreement must be one which deals with core subjects of collective bargaining such as wages and working conditions and which does not directly affect third parties or markets. Accordingly, his conclusion on antitrust immunity for collective agreements was *"that collective agreements between management and labour concluded in good faith on core subjects of collective bargaining such as wages and working conditions which do not directly affect third markets and third parties are not caught by Article 85(1) of the Treaty".*

occasions, applied Article 81(1) EC in the light of a" rule of reason" rather than as an abstract rule. Under a "rule of reason", an anti-competitive practice falls outside the scope of the prohibition in Article 81(1) EC if it has more positive than negative effects on competition on a given market.

74. As far as national regulatory measures in the field of healthcare are concerned, a parallel can be drawn with Wouters[105] *relating to the compatibility with competition law of a regulation of the Bar of the Netherlands prohibiting its members from practising law in integrated partnership with accountants. It should be kept in mind, however, that the Bar was considered by the Court as the regulatory body of a profession exercising an economic activity in the sense of article 81. The regulations of the Bar at stake were therefore not identical to state measures.*

Reviewing the disputed regulation, the Court concluded that, despite the restrictive effects on competition, the prohibition was necessary for the proper practice of the legal profession as organised in the Netherlands. The Court underlined the objectives pursued by the regulation which were here connected with the need to make rules relating to organisation, qualifications, professional ethics, supervision and liability, in order to ensure that the ultimate consumers of legal services and the sound administration of justice are provided with the necessary guarantees in relation to integrity and experience, in the interest of the administration of justice and of the consumer. The Bar had the responsibility to adopt the essential rules to ensure the proper practice of the profession and in particular the rules necessary to oblige members of the Bar to comply with the duty to act for clients in complete independence and in their sole interest, the duty to avoid all risk of conflict of interest and the duty to observe strict professional secrecy. On the contrary, the profession of accountant was not subject to comparable requirements of professional conduct. As a result, there could be an incompatibility between the legal activities carried out by a member of the Bar and the supervisory activities carried out by an accountant. Even though the Court did not expressly confirm the existence of a "rule of reason" within the field of Article 81(1) EC, it implicitly made an application of such a rule in this case, confirming that certain restrictions of competition could escape from Article 81(1) EC on the ground that those restrictions ensure the preservation of fundamental values of the legal profession, i.e. the cohesion of that profession.[106] Transposing the reasoning to this study, the Court's ruling in the Wouters *case demonstrates that a restriction of competition may fall outside the scope of Article 81(1) EC if such a restriction is necessary to ensure the preservation of the cohesion of the national healthcare system.*

F. Rules on state aid

[105] Case C-309/99, judgment of 19 February 2002

[106] See on the application of the rule of reason in the Wouters case, L.Defalque ,L'application des règles de concurrence aux réglementations des orders professionnels, J.T.2002, p.457

1. The mechanism of State Aid control under the EC Treaty:

75. Articles 87 and 88 EC require state aid to be controlled by the Commission.

The principle is that state aid are incompatible with the Common market, but there are very broad and various exceptions to this general prohibition.

76. Article 87 (1) EC states that *"any aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods shall, in so far as it affects trade between Member States, be incompatible with the common market."*

The four conditions required by Article 87(1) EC for categorising a national measure as state aid are:

- the financing of that measure by the State or through State resources,
- the existence of a benefit for an undertaking,
- the selective nature of the said measure, and
- its effect on trade between Member States and the distortion through State resources, of competition resulting there from.

77. Measure imputable to the State and financed through State resources

Legislation on hospital budgets is entirely the responsibility of the Minister for Social Affairs, and the budget is fixed by the Ministry of Social Affairs, Public Health and the Environment.

78. An advantage for the beneficiary

State aid is a measure of the public authorities favouring certain undertakings or certain products.

The concept of aid is wider than that of a subsidy. It may cover any action which, in various forms, mitigates the charges which are normally included in the budget of an undertaking;

The beneficiary must be an undertaking (see above the concept of undertaking).

A controversial question is whether the compensation granted by a Member State to an undertaking in consideration for the public service obligations it has been

entrusted with, has to be regarded as a state aid within the meaning of Article 87(1) EC (see below).

79. The condition of specificity

All sectoral measures are selective. A measure is selective in the sense that it favours a certain category of undertakings (hospitals).

80. Effects on intra-Community trade and competition

The Commission took a decision[107] concerning a measure seeking « to promote the investment in the construction, extension and refurbishment of much needed hospital buildings » in Ireland.

The Commission stated that:

« It must be noted that the measure does not discriminate against providers from other member states which would be required to comply with the same criteria as domestic providers. Furthermore, the measure is not one which benefits hospitals to such an extent that it would in itself be a reason for an operator to decide to create facilities in Ireland rather than in another member state and it will in practice support the creation of relatively small hospitals. Finally, the aim of the measure is to make available additional beds for public health care services at a local level following on from reports criticising the insufficient availability of public health beds. Consequently, although this effect on trade does exist in potential, it can be considered as in effect non-existent in the case at hand since the effect of this measure is to serve the local market, there exists a clear undercapacity in the local hospital market, and it can be considered not to create complexes which will attract customers from other member states".

But it does not mean that all the aids granted to hospitals cannot be considered as affecting trade between Member States.

De minimis aid

An aid granted by a Member State to an enterprise where the amount of aid involved does not exceed 200.000 euros over a three-year period is deemed not to meet all the condition of Article 87 (1) EC since it does not affect trade between Member States and/or does not distort or threaten to distort competition.

81. Procedural rules

[107] Decision C (2002)608fin, 27.02.2002

Pursuant to Article 88 (3) EC, Member States are obliged to notify the Commission of their intention of granting an aid, before they take the final decision to adopt this aid measure. In addition, they must respect a standstill obligation until the Commission decides whether the notified measure constitutes a state aid and, if so, whether such aid is compatible with the common market, i.e. whether it meets the conditions for one of the exemptions provided for in Article 87(2) or (3) EC.

State aid granted in violation of the notification or of the standstill obligations is deemed to be an illegal aid. If the Commission finds out that such illegal aid is moreover incompatible with the Common Market, it will – save exceptional circumstances – order the guilty Member State to recover from the beneficiary the aid amounts (including a commercial interest as from the moment on which the aid was illegally granted).

2. Compensation for public service obligations

82. The issue is whether compensation granted by a Member State to an undertaking in consideration for the public service obligations it has been entrusted with, has to be regarded as a state aid within the meaning of Article 87(1) EC or whether it should be decided that the funding of public service obligations has to be seen as a compensation to their providers and not as an advantage. In the latter case, there is no state aid since the criteria of Article 87(1) EC are not fulfilled.

The debate between the supporters of each of the two approaches has more than an academic interest, since it could have a practical impact. On the one hand, the state aid approach meant that the compensation must be subjected to the prior approval of the European Commission. On the other hand, the compensatory approach meant that the funding measures would entirely escape the control mechanism organised for state aid.

83. For a long time, they were divergent opinions on this question. On 24 July 2003, the European Court of Justice handed down its judgment in the *Altmark* case, ending (?) the controversy surrounding the application of the EC state aid control regime to compensation granted to undertakings in consideration for public service obligations imposed on them.

The Court held that such compensation does not confer a true financial advantage on the undertakings concerned, does not have the effect of putting them in a more favourable competitive position than the undertakings competing with them, and hence does not constitute a state aid within the meaning of the EC Treaty, provided that four relatively stringent conditions are satisfied:

First, the recipient undertaking must actually have public service obligations to discharge, and the obligations must be clearly defined."

"Second, the parameters on the basis of which the compensation is calculated must be established in advance in an objective and transparent manner"

"Third, the compensation cannot exceed what is necessary to cover all or part of the costs incurred in the discharge of public service obligations, taking into account the relevant receipts and a reasonable profit for discharging those obligations."

Fourth, either the undertaking selected to discharge the public service obligation is chosen pursuant to a public procurement procedure, or, failing this, level of compensation is determined "on the basis of an analysis of the costs which a typical undertaking, well run and adequately provided (...) would have incurred in discharging those obligations"

Either the compensation measures comply with the four criteria enunciated by the Court; or the measures are state aid and should be notified to the European Commission.

84. Consequences of the *Altmark* judgment

Through this ruling in *Altmark*, the Court has brought a significant clarification to the treatment of the financing of public services in the European Union.

However some important issues still require further clarification by the Court in order for their scope to be clearly defined:

– "*parameters"* : it is unclear how much flexibility there might be in any particular case. To what extent can a public authority incorporate mechanisms to adjust the public contribution as necessary?
– what constitutes "*reasonable profit"?*
– the second part of the last criterion, i.e. the *"typical undertaking"*: what kind of undertaking could be regarded as a "typical" one? What are the costs of a typical undertaking? Are undertakings in the same sector under an obligation to give insight in their internal documents?

The four conditions are cumulative: compliance with all four conditions is needed to avoid the state aid rules. What if one condition has not been fulfilled? This last issue is important as a significant number of State interventions in favour of public services will probably not benefit from the *Altmark* judgment. Can Article 86 (2) play a role in all cases of state financing of public services that will not

benefit from the *Altmark* rule? Article 86 (2) EC does not enable state aid to public services providers to escape from the notification and standstill.

85. The "*Altmark* package" of the Commission

On 28 November 2005, the Commission adopted a package of measures designed to provide greater legal certainty to the State financing of public services. The purpose of the new measures is to clarify the application of state aid rules to public service compensation that does not satisfy the '*Altmark*' conditions. The first instrument is a decision that will exempt small-scale public funding from the obligation of prior notification. The second instrument is a framework setting out criteria for the assessment of compensation payments that remain subject to notification. We will focus the analysis on the Commission Decision[108]

86. The Decision provides an exemption from notification for:

- public service compensation granted to undertakings with an average pre-tax annual turnover of less than EUR 100 million during the two financial years preceding that in which the service of general economic interest was assigned to them, which receive annual compensation for the services of less than EUR 30 million;
- public service compensation granted to hospitals and social housing undertakings carrying out services of general economic interest

87. But the exemption is not automatic; it will only apply if the responsibility for operation of the service of general economic interest is entrusted to the undertaking by way of an official instrument, which specifies the nature of the public service obligations, the nature of the special rights assigned to the undertaking, the parameters for controlling and reviewing compensation and the arrangements for avoiding and repaying overcompensation.

88. The Decision also provides that the amount of compensation paid shall not exceed what is necessary to cover the costs incurred in performing the public service obligations. It explains how this should be calculated and what revenues and profit allowance should be taken into account.

89. Furthermore, the Decision requires Member States to carry out regular checks to ensure that undertakings are not being over-compensated and contains provisions relating to repayment. Where the amount of over-compensation does not exceed 10 % of the amount of annual compensation, such overcompensation may be carried forward to the next year.

[108] OJ L 312, 29.11.2005

90. Finally, Member States must retain all relevant information about payments made under this Decision and must make reports to the Commission every three years.

91. It is very important to note the terms of the recital (16):

"*Hospitals (…) have specific characteristics that need to be taken into consideration. In particular, account should be taken of the fact that at the current stage of development of the internal market, the intensity of distortion of competition in those sectors is not necessarily proportionate to the level of turnover and compensation. Accordingly, hospitals providing medical care, including, where applicable, emergency services and ancillary services directly related to the main activities, notably in the field of research, should benefit from the exemption from notification provided for in this Decision, even if the amount of compensation they receive exceeds the thresholds laid down in this Decision,* ***if the services performed are qualified as services of general economic interest by the Member States****."*

So it is sufficient that a Member State qualifies the services performed by the hospitals as services of general interest and that any over-compensation of the costs is avoided for the compensation to be compatible with the Treaty. In this respect, it is necessary that the costs that can be reimbursed are determined in a very clear and precise manner.

G. Conclusion

92. In conclusion, considering that provisions of Community law oblige a Member State to demonstrate that an instrument used to organise its health care system is necessary and proportional for maintaining the financial balance of the national social security system as well as for maintaining the essential characteristics of the national system for managing health care, two legal approaches could be considered:

- *A case-by-case approach: continue developing a legal case-by-case reasoning that would allow safeguarding against the interference of community law in individual infringement cases. The main disadvantage of this approach is that in itself it does not create legal certainty regarding the application of community law to national rules on the organisation of health care.*

- *An overall approach: that would consist in restricting the application of the provisions regarding the internal market and competition in the field of health in a European legal instrument. The provisions of the EC treaty regarding the internal market could provide a legal basis. In*

view of the 'tobacco' judgment, Article 95 could indeed provide a legal basis, on the condition that the objective of public health is only secondary. The intention would not be to entirely exclude health care from the application of community law, but rather to codify certain rules that make it possible to clarify the implementation of community law, while fully respecting Member States' responsibilities regarding the organisation and delivery of health services and medical care in accordance with article 152(5) EC.

IV. EC LEGALITY OF A REGULATORY FRAMEWORK ON HEALTH CARE IN THE LIGHT OF THE NEED TO PRESERVE THE COHESION OF NATIONAL HEALTH CARE SYSTEMS

93. It clearly follows from the reasoning set out above that national regulatory instruments to organise and manage health care systems fall within the scope of EC Treaty provisions. As Advocate General Geelhoed stated in the *British American Tobacco* case: *"National statutory measures to protect specific recognized public interests ... constitute a prime example of measures which generate barriers to trade."*[109] Given the fact however that the organisation of national health care systems is embedded in social security systems, Member States have, in justifying barriers to free movement, argued that their regulatory instruments (i.a authorisation schemes) are crucial for maintaining the balance in their social security systems. The Court has recognised on several occasions that the risk of seriously undermining the financial balance of a social security system can constitute an overriding reason in the general interest capable of justifying an obstacle to the freedom to provide services.[110] This overriding reason is directly linked to the justification of "the need to preserve the cohesion of the tax system",[111] as introduced by the Court of Justice in the *Bachmann* case.[112]

> *94. The* Bachmann *case concerned the refusal by the Belgian local tax authorities to allow a German national employed in Belgium the deduction from his total occupational income of contributions paid in Germany pursuant to insurance contracts concluded before his arrival in Belgium. The question before the Court of Justice was whether provisions of Belgian revenue law relating to income tax pursuant to which only sickness and invalidity insurance contributions or pension and life contributions paid in Belgium were deductible were compatible with the EC Treaty provisions on free movement.*[113]

In assessing whether this measure was justified by the need to preserve the cohesion of the tax system, the Court recognised that under the Belgian tax system there was a connection between the deductibility of contributions and the liability to tax of sums payable by insurers under pension and life contracts. In this respect, the Court held that: "...*in such a tax system the loss of revenue resulting from the deduction of life assurance contributions from total taxable income - which includes pensions and insurance payable in the event of death - is offset by the*

[109] C-491/04, *British American Tobacco*, Opinion Advocate General Geelhoed, par 103.
[110] See e.g. C-372/04, *Watts*, par 103.
[111] V.G. Hatzopoulos, "Do the rules on Internal Market Affect National Health Care Systems?" in M. McKee, E. Mossialos and R. Baeten (eds), *The Impact of EU Laws on Health Care Systems*, P.I.E.-Peter Lang, 2002, p.138-9.
[112] C-204/90, *Bachmann*, see also C-300/90, *Commission v Belgium*.
[113] C-204/90, *Bachmann*, par 2-4.

taxation of pensions, annuities or capital sums payable by the insurers. Where such contributions have not been deducted, those sums are exempt from tax.

"The cohesion of such a tax system, the formulation of which is a matter for each Member State, therefore presupposes that, in the event of a State being obliged to allow the deduction of life assurance contributions paid in another Member State, it should be able to tax sums payable by insurers."[114]

*95. The link between the justification of the need to preserve the cohesion of the tax system and the risk of seriously undermining the financial balance of a social security system is clear, since they share the same logic. In both cases, Member States are concerned about limiting the impact of factors "*disturbing the difficult equation between contributions received and moneys paid are circumscribed."[115] *Furthermore, the Court's reasoning according to which the formulation of the cohesion of a particular tax system is a matter for each Member State can easily be transposed to the formulation of the cohesion of a particular health care system that is embedded in a social security system. In both cases, Member States have retained the competence to regulate and have not attributed this competence to the Community.*

The Member States' power in this respect however is not unlimited. In the Bachmann *case, the Court thus stated that* "...as Community law stands at present, it is not possible to ensure the cohesion of such a tax system by means of measures which are less restrictive than those at issue in the main proceedings, and that the consequences of any other measure ensuring the recovery by the State concerned of the tax due under its legislation on sums payable by insurers pursuant to the contracts concluded with them would ultimately be similar to those resulting from the non-deductibility of contributions."[116]

In other words, the measure of the deductibility of contributions paid in Belgium was considered to be the least restrictive measure available to the said Member State which was able to ensure the preservation of the particular tax system. The same reasoning could apply to justify national regulatory measures in the field of healthcare although they limit the free circulation or competition.

[114] C-204/90, *Bachmann*, par 22 and 23.
[115] V.G. Hatzopoulos, *l.c.*, p. 138.
[116] C-204/90, *Bachmann*, par 27. See also C-372/04, *Watts*, in which the Court follows a similar reasoning as regards the prior authorisation procedure for the assumption of health care costs (par 106-110) and C-446/03, *Marks and Spencer*, in which the Court took on board the argument that it was possible to identify other less restrictive measures than a general exclusion from group tax relief but nevertheless concluded that *"such measures in any event require harmonisation rules adopted by the Community legislature."* (par 54-58).

96. As far as competition law is concerned, as already indicated, a parallel could be drawn with the Wouters[117] *case relating to the compatibility with competition law of a regulation of the Bar of the Netherlands prohibiting Bar members to enter into multi-disciplinary partnerships.*

The Court held that the regulation was justified to ensure the proper practice of the profession of lawyers for the benefit of the ultimate consumers of legal services and the sound administration of justice.

Making an "implicit" application of the "rule of reason", the Court concluded that the prohibition, even though it restricted competition, did fall outside the scope of Article 81(1) EC as it ensured the preservation of fundamental values of the legal profession. It seems therefore that the Court's reasoning on the cohesion of a particular tax system in the field of the provision of services could probably be transposed to the application of competition rules to healthcare measures, supposing those State measures would fall within the ambit of competition rules.

97. The development of a global solution defining the limits of the application of EC Treaty rules on internal market and competition in the field of health care will not only require the identification of national regulatory measures that are needed to ensure the cohesion of the national health care/social security system, but also a strict reasoning why these measures are the only measures ensuring the preservation of the cohesion of such a system, less restrictive measures being insufficient to attain the objective.

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[117] C-309/99, judgment of 19 February 2002.