出國報告（出國類別：其他）

赴歐盟執委會參加「國家專家專業訓練計畫」

服務機關：經濟部標準檢驗局
姓名職稱：游嘉倩科員
派赴國家：比利時
出國期間：**105** 年 **10** 月 **1** 日至 **105** 年 **12** 月 **31** 日
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摘要

歐盟執委會(European Commission)舉辦之「國家專家專業訓練計畫（National Experts in Professional Training, NEPTs）」，招募對象為歐盟各會員國之政府官員，我國在「臺歐盟雙邊諮商會議」架構下，洽獲歐盟執委會同意接受我方派員，為少數獲得參訓名額之非歐盟會員國。

歐盟執委會於 2015 年 5 月 6 日正式通過 Digital Single Market (DSM)策略，以因應數位經濟時代，期望改善網路商品及服務之使用、創造適合數位網路及服務之環境及數位化驅動成長。該策略應用於衛生及食品安全領域內，旨在藉由促進數位科技之標準化及互用性，以促進病患、健康系統及產業之利益。

經由實際至衛生暨食品安全總署見習，觀察其工作方式為採取信任員工制及員工自主管理、明確之目標及執行方式及較無行政資源任務重複現象、會議進行正向討論及交流並尊重發言者、較無繁複之工作流程及尋求精簡、重視改善及會後評估及善用圖形或顏色給予明瞭之指示，並建議行政機關建立與利害關係人之固定聯絡及溝通平台、具體之願景、適時評估政策成果及擴大申請國家專家專業訓練計畫之對象。

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壹、目的

歐盟執委會舉辦之「國家專家專業訓練計畫（National Experts in Professional Training, NEPTs）」，旨在藉由歐盟會員國政府派員至歐盟相關總署見習工作，促使參訓官員瞭解歐盟執委會之政策及運作方式，同時運用自身專業知識及工作經驗與見習單位交流。我國在「臺歐盟雙邊諮商會議」架構下，洽獲歐盟執委會同意接受我方派員，為少數獲得參訓名額之非歐盟會員國。

鑒於歐盟在國際間扮演重要角色，其政策制定、工作模式及會員國間溝通協調值得我方參考，我方參與本計畫除可瞭解歐盟執委會運作方式外，並可同時強化臺歐盟實質合作關係。

貳、過程

一、歐盟執委會之國家專家專業訓練計畫簡介

歐盟執委會(European Commission)舉辦之「國家專家專業訓練計畫（National Experts in Professional Training, NEPTs）」，招募對象為歐盟各會員國之政府官員，於實習期間除因執行公務而出差支付相關費用外，將不額外支付錄取之政府官員薪資，且仍屬原政府之受雇者，惟於實習期間其工作條件及工作內容，則依歐盟執委會相關規定辦理及執行。另歐盟執委會亦有針對其歐盟會員國之大學畢業生所招募之藍書實習計畫(Blue Book traineeship)，以獲取實務工作經驗。

我國在「臺歐盟雙邊諮商會議」架構下，洽獲歐盟執委會同意接受我國派員，為少數獲得參訓名額之非歐盟會員國。本計畫依外交部行文詢問各相關部會是否薦員參訓，並依歐盟執委會提供之申請表格式填列欲參訓之前三志願總署(Directorate-General, DG)，由外交部提供歐盟執委會我國之申請者名單，惟我國可否派員參訓須視歐盟執委會相關總署是否核錄，另若申請者非屬歐盟會員國，則無法申請至 DG JUST (Justice and Consumers)、DG HOME (Migration and Home Affairs)及 DG ELARG (European Neighbourhood Policy And Enlargement Negotiations)見習，見習時程亦以 3 個月為限。

由於與現行消費者保護業務領域最相關之單位為 DG JUST 之 Consumers 領域，惟非歐盟會員國無法申請該總署，爰以目標領域較相似之衛生暨食品安全總署 DG SANTE (Health and Food Safety)、成長總署 DG GROW (Internal Market, Industry, Entrepreneurship and SMEs)及資訊總署 DG CNECT(Communications Networks, Content and Technology)為志願予以申請，於獲歐盟執委會通知獲衛生暨食品安全總署核錄後，於參訓首日依歐盟執委會安排，與自各國政府派赴參訓本計畫之政府官員共同參與開訓講習會後，即各自至核錄之總署進行見習。

二、歐洲聯盟(European Union)簡介

(一) 歷史簡說

歐洲聯盟(簡稱歐盟)總部設立於比利時布魯塞爾，其歷史可追朔自1951 年創立之歐洲煤鋼共同體(The European Coal and Steel Community)，創立國分別為比利時、德國、法國、義大利、盧森堡及荷蘭，由於第二次世界大戰產生之創傷，其建立目的係為確保戰勝國及戰敗國間之和平，後於 1957 年成立歐洲原子能共同體(European Atomic Energy Community, Euratom)及歐洲經濟共同體(European Economic Community, EEC)，並於 1968 年廢除關稅及於 1960 年代實行貿易及農業之共同政策。於 1992 年實現歐洲單一市場，1993 年馬斯垂克條約(The Treaty of Maastricht)生效並創立歐洲聯盟，2009 年里斯本條約(The Lisbon Treaty)生效，並改變歐盟之運作模式。

(二) 任務宗旨

歐盟成立至今，其主要任務如下：

- 維持並建立會員國間之和平。
- 建立歐洲國家之實質合作。
- 確保歐洲公民之居住安全。
- 促進經濟及社會團結。
- 在全球化下，保存歐洲之特性及多樣性。
- 傳揚歐洲共享之價值。

(三) 組織架構

歐盟是一獨特組織，創立單一貨幣歐元，使其建立之貨品及服務單一市場更為效率，各會員國將部分主權授權予更高機構辦理政策決定，惟歐盟並非聯邦國家，目前設立之機構如下：

- 歐洲理事會(The European Council)：為歐盟最高決策機構，其組成之成員為各會員國之國家元首或政府首長及歐盟執委會主席，訂立

歐盟之總體方向及優先事項。

- 歐盟理事會(The Council)：組成成員為各會員國政府部長，其主要任務為決定政策及通過歐盟法律。
- 歐洲議會(The European Parliament)：歐洲議會成員係由歐盟公民直接選舉產生，代表人民的聲音，各國成員人數配額係依各會員國人口數分配。歐洲議會與歐盟理事會共同擁有通過歐盟法律及審預算之權利，並監督歐盟所有機構。
- 歐盟執委會(The European Commission)：歐盟之行政機構，其主要任務為提案法律、執行政策及預算、強化歐盟法律及於國際間代表歐盟。
- 歐洲法院(The Court of Justice)：為司法機構，其角色為確保歐盟法律及條約被正確的詮釋及應用。
- 歐洲中央銀行(The European Central Bank)：負責管理歐元及貨幣政策，主要任務為保持物價穩定及監督歐元區之銀行。
- 歐洲審計院(The Court of Auditors)：確認預算之募集及運用之正確性，及改進歐盟財務管理。
- 經濟及社會委員會(The European Economic And Social Committee)：組成成員代表著不同經濟及社會之利益團體，當政策決定涉及多領域時，歐盟理事會及歐盟執委會可能向其諮詢。
- 區域委員會(The Committee of The Regions)：組成成員為區域或當地政府代表，當政策涉及該區域時，歐盟理事會及歐盟執委會可能向其諮詢。
- 歐洲投資銀行(The European Investment Bank)：任務為提供投資之貸款及支援歐盟之目標。

(四) 法律架構

歐盟法律分為基本法(Primary Legislation)及次級法(Secondary

Legislation)，條約即是基本法，係歐盟所有行動之基礎；次級法則分別為規則(Regulation)、指令(Directive)及決定(Decision)，皆源自於條約所設立之原則及目標。歐盟政策決定牽涉其設立之各機構，如歐洲議會(The European Parliament)、歐盟理事會(The Council)及歐盟執委會(The European Commission)，法律工具及立法流程簡述如下：

- 法律工具：

  規則(Regulation)：規則具有約束力，可直接適用於各會員國，且各會員國毋須轉換其為各會員國之國家法律，即便各會員國可能需要修正其國家法律，以避免與該規則產生衝突。

  指令(Directive)：指令對各會員國就為達成特定之目標具有約束力，至於如何設計其法律以達成該目標則由各會員國各自決定。

  決定(Decision)：決定對特定相對人具有約束力且具有直接適用性。

  建議及意見(Recommendations and Opinions)：建議及意見分別係歐盟機構發表之行為建議及陳述說明，惟此法律工具並無具有法律義務即無約束力。

- 普通法立法程序：

  在歐盟執委會提交法律提案予歐洲議會前，歐盟執委會進行潛在之經濟、社會及環境之影響評估，闡述各政策可能產生之優勢及劣勢。歐盟執委會亦諮詢與該政策相關之非政府組織、產業代表及當地機構等，以確保立法提案符合該案相關人之需求及避免官僚主義。

  公民、企業或組織等亦可經由公開諮詢網站參與諮詢程序，各國內議員若認為該議題應以國內而非歐盟層級方式處理較適當，亦可表述其意見。有關普通法立法程序如下：

  步驟 1. 歐盟執委會提案：歐盟執委會提交法律提案予歐洲議會。

  步驟 2. 歐洲議會一讀：歐洲議會檢視該提案後決議同意或要求修

正。

步驟 3. 歐盟理事會一讀：若歐盟理事會同意歐洲議會意見，該提案則通過；若修正歐洲議會之意見，則交回提案予歐洲議會進行二讀。

步驟 4. 歐洲議會二讀：若歐洲議會同意歐盟理事會意見，該提案則通過；若不同意，該提案則不會生效且停止該提案之立法程序；若要求修正，則交回提案予歐盟理事會進行二讀。

步驟 5. 歐盟理事會二讀：檢視歐洲議會二讀之修正意見，若同意則提案通過；若不同意修正意見，則進入調解程序。

步驟 6. 調解程序：調解委員會由同樣人數之歐洲議會成員及歐盟理事會成員組成，若未成功，則提案不會生效且停止該提案之立法程序；若達成同意，則交回歐洲議會及歐盟理事會進行三讀。

步驟 7-1. 歐洲議會三讀：檢視條文並進行全體表決，若不同意，則提案不會生效且停止該提案之立法程序；若同意且歐盟理事會亦三讀同意，則提案通過。

步驟 7-2. 歐盟理事會三讀：進行條文檢視，若不同意，則提案不會生效且停止該提案之立法程序；若同意且歐洲議會亦三讀同意，則提案通過。

當歐盟理事會及歐洲議會通過立法提案(規則、指令及決定)，則由該二機構之主席及秘書長簽屬，並進行正式公布。

圖 1：歐盟會員國位置圖

資料來源：

http://bookshop.europa.eu/en/how-the-european-union-works-pbNA0414810/

三、見習單位衛生暨食品安全總署(DG SANTE)簡介

(一) 組織簡介

歐盟執委會為歐盟之行政機關，其轄下分別有 31 個總署(Directorate-General)、16 個服務部門(Service Department)及 6 個經辦處(Executive Agency)。目前共有約 3 萬位員工。

歐盟執委會之衛生暨食品安全總署(DG Health and Food Safety, DG

SANTE)，係屬歐盟執委會較具規模之總署，領域為衛生、食品、動物及植物之管理，其目標為保護及改進公共健康、確保食品安全及合乎衛生及保護動物、植物及森林之健康，其內部單位共設有7個司(Directorate A 至 Directorate G)及 1 個執行機構(Consumer, Health, Agriculture and Food Executive Agency)，各司下設有處(Unit)，每司具有 1 個至 7 個不等的處，本次見習獲派至 Directorate B：Health Systems, Medical Products and Innovation 進行見習。

(二) Digital Single Market 策略

歐洲面臨網路商品及服務仍係以國內為主，跨境網路商品及服務仍尚未普遍之現象，為因應數位經濟時代，歐盟執委會於 2015 年 5 月 6 日正式通過 Digital Single Market (DSM)策略，且將貢獻經濟成長、增加工作機會及改善公共服務。策略共包含「改善網路商品及服務之使用」、「創造適合數位網路及服務之環境」及「數位化驅動成長」3 部分。

該策略應用於衛生及食品安全領域內，旨在藉由促進數位科技之標準化及互用性，以促進病患、健康系統及產業之利益，在該策略下，衛生暨食品安全總署制定 2012 年至 2020 年之 eHealth 行動計畫，eHealth 係指運用資訊及通訊科技(Information and Communication Technologies, ICTs)，以改善預防、診斷、治療及監控等。eHealth 包含病患、健康照護服務提供者、醫院及醫療領域專家間的資訊資料交換、電子病歷、遠距醫療服務、可攜式病患監控設備及機器人手術等。為達目標，其運用工具如下：

- eHealth Network：在跨境健康照護指令(Cross-Border Healthcare Directive)下，給予病患於其他歐盟會員國接受醫學治療之權利。eHealth Network 組成之成員為各會員國之政府官員，以強化電子健康系統及照護連貫性間的互用性及確保安全及品質健康照護之使用。

- Joint Action：給予 eHealth Network 技術上及科學上之支援，以實現 eHealth Network 之年度工作計畫，其主要聚焦於 eHealth 數位服務公共建設之建立。
- European Reference Network：促進革新之臨床解決方案、診斷之新可能性、更有效之治療等。組成成員為醫院及專業研究者等。
- Stakeholders：歐盟執委會積極地與利害關係人聯繫，以強化利害關係人對使用數位健康服務之信心，利害關係人團體亦對 eHealth 政策之發展及執行提供貢獻。
- Financing Instrument：資金來源除歐盟執委會編列之預算外，亦對外進行募款，資金除運用於執行政策外，亦支援研究計畫、健康領域下資訊及通訊技術之創新及合作、協助中小企業提升 eHealth 解決方案規模及尋找海外市場、建置 eHealth 之數位公共建設等。
- eHealth Digital Service Infrastructure：建置數位服務公共建設，以使病患資料能於不同會員國間進行交換，如：電子病情摘要及電子處方箋。歐盟執委會亦提供如何建置該公共建設之指導方針予會員國。
- 大數據研究：委託外部單位執行研究報告，期望經由大數據研究以取得政策建議及行動。

經由行動計畫之執行，爾後，經由電子處方箋，病患可於其他歐盟會員國取得藥物，健康照護專家經由取得電子病情摘要，病患亦可於其他歐盟會員國接受醫學治療。

後續透過詢問共事之同事，衛生暨食品安全總署之角色為促進、協助會員國執行以達成 eHealth 之目標，並有監督機制以瞭解會員國是否符合規定，若會員國違反規定，亦將有受到處分之可能性。

然而，執行 eHealth 政策亦面臨眾多挑戰，國家健康系統之數位化及整合、以醫生為中心轉換為以病患為中心之醫療照護之典範轉移、高

齡化社會、健康照護之不均等及病患資料屬高度敏感資料，如何保護隱私權皆屬重要議題。

四、見習內容

(一) 參與各項會議：

- 每周例行單位會議(會議的記錄採輪流制，獲分派撰寫其中一周會議之會議紀錄)
- 每周例行團隊會議
- eHealth Stakeholder Group meeting(協助撰寫會議紀錄)
- IN SILICO − Turning Big Data Into Personalized Medicine(協助撰寫會議紀錄)
- Public Hearing − "Towards An mHealth Framework For Europe"
- Conference on Cross-Border Healthcare Directive − "Towards Amplified Awareness of EU Rights to Cross-Border Care"
- 10th Meeting of the eHealth Network
- The 3D printing Revolution and The Dental Sector − Opportunities and Challenges(協助撰寫會議紀錄)
- Knowledge Hour on Better Regulation – Introduction to the Intervention Logic

見習之單位，員工若參加外部研討會，皆撰寫簡易會議紀錄或記載重要議題，並將該紀錄以電子郵件傳送予相關人員參考或於每周例行單位會議進行分享。

歐盟執委會經常辦理各式研討會，邀請相關行政總署及產業代表，就研討主題各自進行簡報及意見交流，若獲分派撰寫研討會紀錄，任務則為記錄產業代表之意見，及回報產業代表是否表示有修正或訂立相關法規需求。

(二) 搜尋並彙整各會員國執行成果報告：

由於至衛生暨食品安全總署見習期間，恰逢見習單位正進行 eHealth 行動計畫，且規劃於 2018 年達成第一筆電子資料交換，需適時檢視會員國執行情形，爰獲指示於相關專業網站蒐集各會員國目前執行 eHealth 之成果報告，以瞭解執行結果與目標間之差距，供見習單位之 eHealth 團隊作為後續行動之參考。

彙整最主要功能係為整理各報告含有之「指標(Indicator)」，指標係以質化或量化方式衡量現行成果與目標之距離，以協助衛生暨食品安全總署分析並比較各會員國間之執行成果，且亦可協助訂定政策之優先事項。指標係以可信賴及可比較之資料為基礎，對於衛生暨食品安全總署設計策略及政策以促進歐盟公民健康及監控會員國執行情形，亦係不可或缺的。

經由彙整相關報告，其指標含有使用網路頻率、電子紀錄及健康資訊交換之使用及可得性、電信科技之使用及可得性以支援健康照護及法律基礎架構等。

(三) 簡報見習成果：

於見習將屆時，亦繳交見習報告予見習單位，及與見習單位主管就獲分派業務之執行成果及個人觀察事項進行討論，並將該內容於例行單位會議進行簡報與同仁分享。

有關獲分派業務之執行成果，除向見習單位主管討論自各專業網站彙整之各會員國目前執行 eHealth 成果報告含有之指標及顯示彙整結果外，並向見習單位主管表示哪些指標是重要且需要的，亦屬進行下一步驟前須釐清事項。此外，如欲瞭解會員國執行情形與目標之差距，除自相關專業網站搜尋報告外，亦可建立問卷以獲取所需資訊，其中經濟合作暨發展組織(Organisation for Economic Co-operation and Development, OECD)發布之 DRAFT Guide to Measuring ICTs in the Health Sector，其問卷設計內容最具參考價值。

個人觀察事項部分，則向其分享我國與歐盟執委會工作模式之不同處，及自歐盟執委會學習之事項進行交流。

(四) 協助駐歐盟兼駐比利時代表處與見習單位主管餐敘：

在駐歐盟兼駐比利時代表處主管及同仁邀請下，協助聯繫見習單位主管共同至位於布魯塞爾之臺灣餐館餐敘，就本見習計畫建議及未來相關合作事項及可能性進行交流及討論，以期強化雙方之合作情誼。

參、心得與建議

一、心得

經由實際赴歐盟執委會衛生暨食品安全總署見習，與該總署員工共同參與行政工作，就其工作方式及文化觀察如下：

(一) 採取信任員工制及員工自主管理：

彈性工時及毋須執行上下班打卡，歐盟執委會之工作時間為每周40小時，核心工作時間為上午9點30至上午12時及下午3點至下午4點30(若為星期三及星期五，下午核心時間為下午3點至下午4點)，並由員工自行至出缺勤系統登錄每日工作時數。

員工電子信箱之行事曆開放予單位內員工查看，參與外部會議僅需於該行事曆載明行程即可，無需如同我國需申請出差勤紀錄核可後方可外出。

員工具有申請 teleworking 福利，員工毋須於辦公室辦公，若有會議，該員工則經由電話或視訊共同參與。

(二) 明確之目標與執行方式及較無行政資源任務重複現象：

經由參與見習單位之 eHealth 行動計畫，在歐盟執委會之 Digital Single Market 大方針政策下，就見習單位之衛生及食品安全領域具有交換電子病情摘要及電子處方箋之具體目標，另如前簡介，為達 eHealth 之目標，其執行工具亦各有其角色及功能，較無行政資源任務重複之現象。

(三) 會議進行正向討論及交流並尊重發言者

就本身參與之 eHealth Stakeholder Group meeting，除主辦方衛生及食品安全總署員工給予業務簡報外，會議出席者即利害關係人亦提供簡報表達概念及意見，雙方進行正向交流。另出席者亦運用會議休息餐敘時間就議題進行交流。

若出席者欲表達意見而其他出席者正在發表意見之情形，該欲接續表達意見之出席者，則豎起位於其前方之名牌，使主席察覺且未打擾正進行意見發表之出席者。

(四) 較無繁複之工作流程及尋求精簡：

辦理非內部會議之承辦人所準備之對外簡報內容，毋須經由簽核程序即可於會議向出席者進行報告。此亦可說明歐盟執委會採取信任員工之文化。工作亦以討論、腦力激盪方式思考解決方式，未有繁複公文簽核程序之現象，爰員工較可專心處理重要事務，較無需花費時間處理其他繁雜事務。另會議紀錄內容尋求重點及精簡模式撰寫。

(五) 重視改善及會後評估

見習單位承辦之對外會議結束後，由單位主管及團隊成員就會議執行情形進行正向討論，分享成功及可改進之處，以作為下次舉行對外會議之參考。

(六) 善用圖形或顏色給予明瞭之指示

由於力求簡易明瞭之文化，歐盟執委會之文件或簡報內容表達方式較易理解其整體架構，進而較可輕易搜尋所需之文件。

二、建議

東方與西方文化及民族性等原因不同，產生工作方式亦不相同之結果，雖適合西方文化之方式不盡然適合我國，且歐盟執委會角色亦較偏向服務及促進會員國執行及達成目標，並有監督機制，與我國屬政府機關不盡相同，惟就藉由赴歐盟執委會衛生暨食品安全總署見習之觀察，值得參考學習事項建議如下：

(一) 建立與利害關係人之固定聯絡及溝通平台：

由於見習單位積極與利害關係人聯繫，定期辦理會議討論議題，雙方亦互相給予簡報，且具有專屬網路溝通平台供上傳文件或意見交流等，

雙方進行正向交流。

鑑於國家政策之執行及其成效，常需長時間之驗證及隨環境變化不斷修正，我國制定政策亦有舉行說明會等模式與利害關係人進行討論，惟會議時間有限，且雙方立場及政策內容非短期間即可通盤理解，建議固定與該政策或事務之利害關係人進行交流(如例行交流會議，雙方針對現況予以簡報)或建立固定溝通平台(如網路平台)，以期政府及利害關係人間產生正向溝通關係，利害關係人間亦可藉由平台交換意見，使政策制定更趨共識決及減少偏誤。

(二) 具體之願景

從歐盟執委會之 Digital Single Market 大方針策略，至衛生暨食品安全總署制定之 eHealth 目標及計畫，可察覺其政策之貫徹性及具體性。

至見習單位參與之團隊，雖較偏向屬任務型之型態(達成 eHealth 目標)，與一般行政機關具有大量之例行工作不盡相同，且例行工作亦係維持國家運作之重要基礎，惟若國家政策方針可具體性使一般行政機關具有清楚執行目標，則較易達成改善現況之目的。

(三) 適時評估政策成果

衛生暨食品安全總署執行計畫期間，意識需適時瞭解各會員國之執行情形與目標之差距為何，便著手進行分析。

由於我國任一政策及事務牽涉之機關眾多，如何整合及合作並有效傳達相關人員，以達成具有像歐盟執委會適時檢視政策成果之彈性，值得我國參考。

(四) 擴大申請國家專家專業訓練計畫之對象

考量我國外交困境，接觸國際事務不易，亦或說更需要提升我國能見度，藉由實際與國外人士共事，除可深入瞭解不同文化背景之工作模式外，亦可啟發對我國現行工作方式之省思，由於現行申請至歐盟執委

會參與國家專家專業訓練計畫為中央政府之員工，建議非屬中央政府員工亦能獲知本見習計畫之訊息，提高全國政府員工參與國際事務之機會。

肆、後記

歐盟執行嚴謹之安全政策

由於歐洲正面臨恐怖攻擊之威脅，赴歐盟執委會參與本見習計畫期間，歐盟之安全部門皆對參訓者進行安全簡報及說明，並請參訓者謹慎對待工作證及所獲得之文件，至其他總署或辦公大樓參與會議前，亦須通過安檢方可進入。

計畫名稱以英文首字母縮略詞表示(acronym)

歐盟執委會之計畫名稱或任一名稱，慣以各英文首字母縮略詞表示，由於中文及英文之邏輯不相同，中文之計畫簡稱，仍可就其簡稱猜測其完整名稱，惟英文係以各單字之首字母表示 (如 eHealth Network 以 eHN 表示)，初期無法僅以該簡略表示猜測其代表之名稱，爰欲瞭解各領域內容及來龍去脈前，需先花時間熟悉各縮略詞所代表之名稱。

多國語言環境

歐盟執委會員工來自其各個會員國，除會議或正式場合係以英文溝通外，員工亦於工作場合以法文、荷蘭文、德文等各國語言進行交談。重大會議場合亦有各國語言同步翻譯設備，以方便出席者參與。

整合以期團結力量大及居民福祉最大化

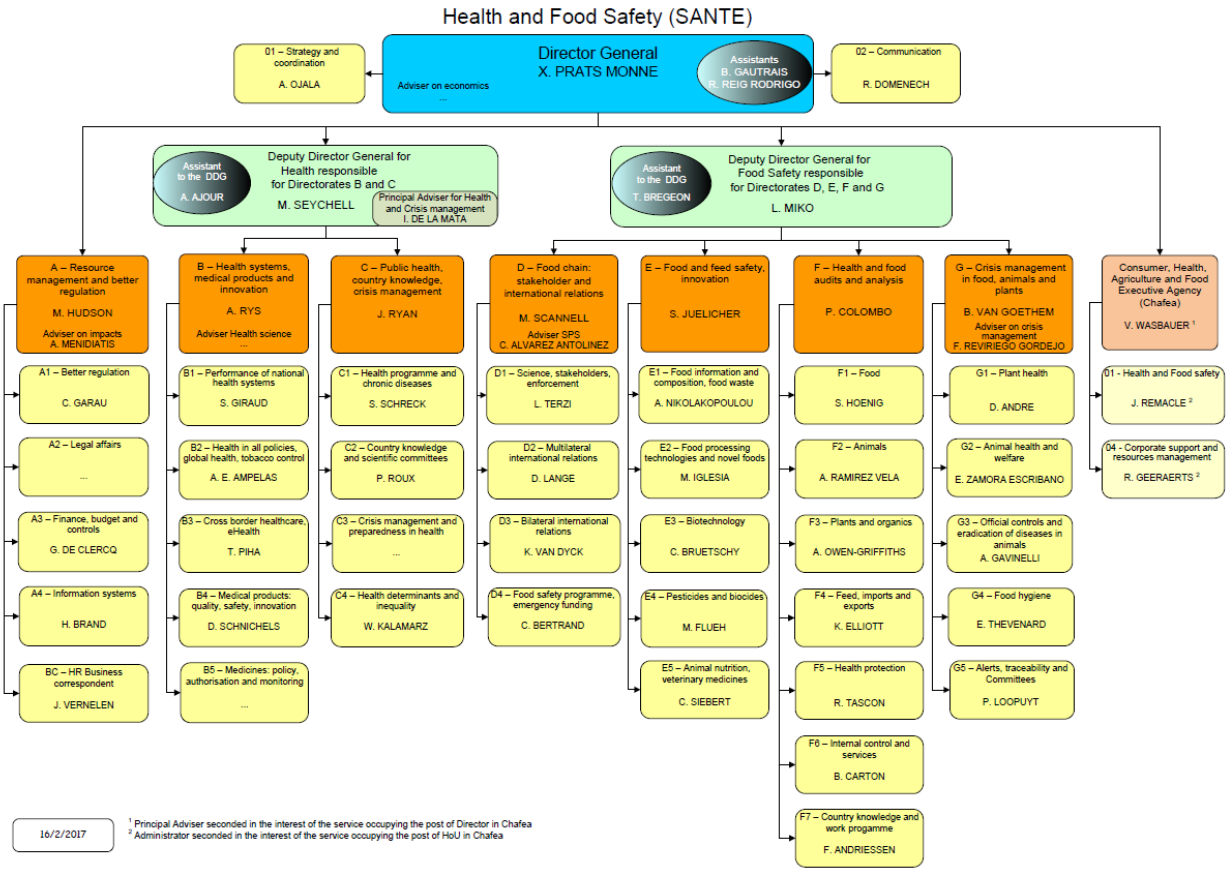
歐盟目前尚具有 28 個會員國，各會員國具有不同經濟程度、文化及語言，雖無法確保任一國際組織皆永久存在，歐盟成立初衷亦係因世界大戰造成巨大傷害，為防止戰爭以期望維持和平，然其面臨複雜環境亦試圖整合以期團結力量大及居民福祉最大化，值得我國省思。

生活品質與工作兼具

歐盟執委會不具有長工時之現象，工作氣氛亦相對輕鬆，歐洲整體社會經濟發展程度仍較進步及善於解決問題，如何著重重要事務，以最簡明有效之方式達成目標，重視意見討論交流及鼓勵創意，非以防弊角度規範員工，值得思考及學習。

伍、附錄

附錄一、衛生暨食品安全總署組織圖



附錄二、見習證明

EUROPEAN COMMISSION
DIRECTORATE-GENERAL
HUMAN RESOURCES AND SECURITY
Directorate HR.DDG.B : Talent Management & Diversity
Career Management & Mobility

Brussels, 24/08/16
HR.DDG.B.4

European Commission
National Experts in Professional Training Programme

ATTESTATION

It is certified that Mrs YU Chia Chien

Born 25/04/1986

of Taiwanese nationality

is on cost-free professional training at the European Commission in Brussels.

Throughout this period, the above-mentioned person remains in service paid by the home employer and subject to the social security legislation applicable to the civil service of the employer which will assume responsibility for expenses incurred abroad.

NAME OF THE EMPLOYER: Ministry of Economic Affairs

STATUS: Civil Servant

DURATION OF PROFESSIONAL TRAINING: from 01/10/2016 to 31/12/2016

COMMISSION EUROPEENNE
Secteur

Marie-Hélène PRADINES
Head of Unit

B-1049 Brussels - Belgium
Telephone: direct line +32 229-65934, switchboard 299.11.11, Email : HR-ENFP@ec.europa.eu

DIRECTIVES

DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 9 March 2011

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 168 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee ([1]),

Having regard to the opinion of the Committee of the Regions ([2]),

Acting in accordance with the ordinary legislative procedure ([3]),

Whereas:

(1) According to Article 168(1) of the Treaty on the Functioning of the European Union (TFEU), a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities. This implies that a high level of human health protection is to be ensured also when the Union adopts acts under other Treaty provisions.

(2) Article 114 TFEU is the appropriate legal basis since the majority of the provisions of this Directive aim to improve the functioning of the internal market and the free movement of goods, persons and services. Given that the conditions for recourse to Article 114 TFEU as a legal basis are fulfilled, Union legislation has to rely on this legal basis even when public health protection is a decisive factor in the choices made. In this respect, Article 114(3) TFEU explicitly requires that, in achieving harmonisation, a high level of protection of human health is to be guaranteed taking account in particular of any new development based on scientific facts.

(3) The health systems in the Union are a central component of the Union's high levels of social protection, and contribute to social cohesion and social justice as well as to sustainable development. They are also part of the wider framework of services of general interest.

(4) Notwithstanding the possibility for patients to receive cross-border healthcare under this Directive, Member States retain responsibility for providing safe, high quality, efficient and quantitatively adequate healthcare to citizens on their territory. Furthermore, the transposition of this Directive into national legislation and its application should not result in patients being encouraged to receive treatment outside their Member State of affiliation.

(5) As recognised by the Council in its Conclusions of 1-2 June 2006 on Common values and principles in European Union Health Systems ([4]) (hereinafter the 'Council Conclusions') there is a set of operating principles that are shared by health systems throughout the Union. Those operating principles are necessary to ensure patients' trust in cross-border healthcare, which is necessary for achieving patient mobility as well as a high level of health protection. In the same statement, the Council recognised that the practical ways in which these values and principles become a reality vary significantly between Member States. In particular, decisions about the basket of healthcare to which citizens are entitled and the mechanisms used to finance and deliver that healthcare, such as the extent to which it is appropriate to rely on market mechanisms and competitive pressures to manage health systems, must be taken in the national context.

(6) As confirmed by the Court of Justice of the European Union (hereinafter the 'Court of Justice') on several occasions, while recognising their specific nature, all types of medical care fall within the scope of the TFEU.

([1]) OJ C 175, 28.7.2009, p. 116.
([2]) OJ C 120, 28.5.2009, p. 65.
([3]) Position of the European Parliament of 23 April 2009 (OJ C 184 E, 8.7.2010, p. 368), position of the Council at first reading of 13 September 2010 (OJ C 275 E, 12.10.2010, p. 1), position of the European Parliament of 19 January 2011 (not yet published in the Official Journal) and decision of the Council of 28 February 2011.

([4]) OJ C 146, 22.6.2006, p. 1.

(7) This Directive respects and is without prejudice to the freedom of each Member State to decide what type of healthcare it considers appropriate. No provision of this Directive should be interpreted in such a way as to undermine the fundamental ethical choices of Member States.

(8) Some issues relating to cross-border healthcare, in particular reimbursement of healthcare provided in a Member State other than that in which the recipient of the care is resident, have already been addressed by the Court of Justice. This Directive is intended to achieve a more general, and also effective, application of principles developed by the Court of Justice on a case-by-case basis.

(9) In the Council Conclusions, the Council recognised the particular value of an initiative on cross-border healthcare ensuring clarity for Union citizens about their rights and entitlements when they move from one Member State to another, in order to ensure legal certainty.

(10) This Directive aims to establish rules for facilitating access to safe and high-quality cross-border healthcare in the Union and to ensure patient mobility in accordance with the principles established by the Court of Justice and to promote cooperation on healthcare between Member States, whilst fully respecting the responsibilities of the Member States for the definition of social security benefits relating to health and for the organisation and delivery of healthcare and medical care and social security benefits, in particular for sickness.

(11) This Directive should apply to individual patients who decide to seek healthcare in a Member State other than the Member State of affiliation. As confirmed by the Court of Justice, neither its special nature nor the way in which it is organised or financed removes healthcare from the ambit of the fundamental principle of the freedom to provide services. However, the Member State of affiliation may choose to limit the reimbursement of cross-border healthcare for reasons relating to the quality and safety of the healthcare provided, where this can be justified by overriding reasons of general interest relating to public health. The Member State of affiliation may also take further measures on other grounds where this can be justified by such overriding reasons of general interest. Indeed, the Court of Justice has laid down that public health protection is among the overriding reasons of general interest that can justify restrictions to the freedom of movement envisaged in the Treaties.

(12) The concept of 'overriding reasons of general interest' to which reference is made in certain provisions of this Directive has been developed by the Court of Justice in its case-law in relation to Articles 49 and 56 TFEU and may continue to evolve. The Court of Justice has held on a number of occasions that overriding reasons of general interest are capable of justifying an obstacle to the freedom to provide services such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources. The Court of Justice has likewise acknowledged that the objective of maintaining a balanced medical and hospital service open to all may also fall within one of the derogations, on grounds of public health, provided for in Article 52 TFEU, in so far as it contributes to the attainment of a high level of health protection. The Court of Justice has also held that such provision of the TFEU permits Member States to restrict the freedom to provide medical and hospital services in so far as the maintenance of treatment capacity or medical competence on national territory is essential for public health.

(13) It is clear that the obligation to reimburse costs of cross-border healthcare should be limited to healthcare to which the insured person is entitled according to the legislation of the Member State of affiliation.

(14) This Directive should not apply to services the primary purpose of which is to support people in need of assistance in carrying out routine, everyday tasks. More specifically, this Directive should not apply to those long-term care services deemed necessary in order to enable the person in need of care to live as full and self-determined a life as possible. Thus, this Directive should not apply, for example, to long-term care services provided by home care services, in assisted living facilities and in residential homes or housing ('nursing homes').

(15) Given their specificity, access to and the allocation of organs for the purpose of organ transplants should fall outside the scope of this Directive.

(16) For the purpose of reimbursing the costs of cross-border healthcare, this Directive should cover not only the situation where the patient is provided with healthcare in a Member State other than the Member State of affiliation, but also the prescription, dispensation and provision of medicinal products and medical devices where these are provided in the context of a health service. The definition of cross-border healthcare should cover both the situation in which a patient purchases such medicinal products and medical devices in a Member State other than the Member State of affiliation and the situation in which the patient purchases such medicinal products and medical devices in another Member State than that in which the prescription was issued.

(17) This Directive should not affect Member States' rules concerning the sale of medicinal products and medical devices over the Internet.

(18) This Directive should not give any person an entitlement to enter, stay or reside in a Member State in order to receive healthcare in that State. Where the stay of a person on the territory of a Member State is not in accordance with the legislation of that Member State concerning the right to enter or stay on its territory, such person should not be regarded as an insured person according to the definition in this Directive. Member States should continue to be able to specify in their national legislation who is considered as an insured person for the purposes of their public healthcare scheme and social security legislation as long as the patients' rights set out in this Directive are secured.

(19) When a patient receives cross-border healthcare, it is essential for the patient to know in advance which rules will be applicable. The rules applicable to cross-border healthcare should be those set out in the legislation of the Member State of treatment, given that, in accordance with Article 168(7) TFEU, the organisation and delivery of health services and medical care is the responsibility of the Member States. This should help the patient in making an informed choice, and should avoid misapprehension and misunderstanding. It should also establish a high level of trust between the patient and the healthcare provider.

(20) In order to help patients to make an informed choice when they seek to receive healthcare in another Member State, Member States of treatment should ensure that patients from other Member States receive on request the relevant information on safety and quality standards enforced on its territory as well as on which healthcare providers are subject to these standards. Furthermore, healthcare providers should provide patients on request with information on specific aspects of the healthcare services they offer and on the treatment options. To the extent that healthcare providers already provide patients resident in the Member State of treatment with relevant information on those specific aspects, this Directive should not oblige healthcare providers to provide more extensive information to patients from other Member States. Nothing should prevent the Member State of treatment from also obliging other actors than the healthcare providers, such as insurance providers or public authorities, to provide the information on specific aspects of the healthcare services offered, if that would be more appropriate with regard to the organisation of its healthcare system.

(21) In its Conclusions the Council recognised that there is a set of common values and principles that are shared across the Union about how health systems respond to the needs of the population and patients that they serve. The overarching values of universality, access to good quality care, equity, and solidarity have been widely acknowledged in the work of various Union institutions. Therefore, Member States should also ensure that these values are respected with regard to patients and citizens from other Member States, and that all patients are treated equitably on the basis of their healthcare needs rather than on the basis of their Member State of affiliation. In doing so, Member States should respect the principles of free movement of persons within the internal market, non-discrimination, inter alia, with regard to nationality and necessity and proportionality of any restrictions on free movement. However, nothing in this Directive should oblige healthcare providers to accept for planned treatment patients from other Member States or to prioritise them to the detriment of other patients, for instance by increasing the waiting time for treatment of other patients. Inflows of patients may create a demand exceeding the capacities existing in a Member State for a given treatment. In such exceptional cases, the Member State should retain the possibility to remedy the situation on the grounds of public health, in accordance with Articles 52 and 62 TFEU. However, this limitation should be without prejudice to Member States' obligations under Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems [1].

(22) Systematic and continuous efforts should be made to ensure that quality and safety standards are improved in line with the Council Conclusions and taking into account advances in international medical science and generally recognised good medical practices as well as taking into account new health technologies.

(23) Ensuring clear common obligations in respect of the provision of mechanisms for responding to harm arising from healthcare is essential to prevent lack of confidence in those mechanisms being an obstacle to taking up cross-border healthcare. Systems for addressing harm in the Member State of treatment should be without prejudice to the possibility for Member States to extend the coverage of their domestic systems to patients from their country seeking healthcare abroad, where this is more appropriate for the patient.

(24) Member States should ensure that mechanisms for the protection of patients and for seeking remedies in the event of harm are in place for healthcare provided on their territory and that they are appropriate to the nature and extent of the risk. However, it should be for the Member State to determine the nature and modalities of such a mechanism.

[1] OJ L 166, 30.4.2004, p. 1.

(25) The right to the protection of personal data is a fundamental right recognised by Article 8 of the Charter of Fundamental Rights of the European Union. Ensuring continuity of cross-border healthcare depends on transfer of personal data concerning patients' health. These personal data should be able to flow from one Member State to another, but at the same time the fundamental rights of the individuals should be safeguarded. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1] establishes the right for individuals to have access to their personal data concerning their health, for example the data in their medical records containing such information as diagnosis, examination results, assessments by treating physicians and any treatment or interventions provided. Those provisions should also apply in the context of cross-border healthcare covered by this Directive.

(26) The right to reimbursement of the costs of healthcare provided in another Member State by the statutory social security system of patients as insured persons has been recognised by the Court of Justice in several judgements. The Court of Justice has held that the Treaty provisions on the freedom to provide services include the freedom for the recipients of healthcare, including persons in need of medical treatment, to go to another Member State in order to receive it there. The same should apply to recipients of healthcare seeking to receive healthcare provided in another Member State through other means, for example through eHealth services.

(27) In accordance with the principles established by the Court of Justice, and without endangering the financial balance of Member States' healthcare and social security systems, greater legal certainty as regards the reimbursement of healthcare costs should be provided for patients and for health professionals, healthcare providers and social security institutions.

(28) This Directive should not affect an insured person's rights in respect of the assumption of costs of healthcare which becomes necessary on medical grounds during a temporary stay in another Member State according to Regulation (EC) No 883/2004. In addition, this Directive should not affect an insured person's right to be granted an authorisation for treatment in another Member State where the conditions provided for by Union regulations on the coordination of social security systems are met, in particular by Regulation (EC) No 883/2004 or Council Regulation (EEC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community [2], which are applicable by virtue of Regulation (EU) No 1231/2010 of the European Parliament and of the Council of 24 November 2010 extending Regulation (EC) No 883/2004 and Regulation (EC) No 987/2009 to nationals of third countries who are not already covered by these Regulations solely on the ground of their nationality [3] and Council Regulation (EC) No 859/2003 of 14 May 2003 extending the provisions of Regulation (EEC) No 1408/71 and Regulation (EEC) No 574/72 to nationals of third countries who are not already covered by those provisions solely on the ground of their nationality [4].

(29) It is appropriate to require that also patients who seek healthcare in another Member State in other circumstances than those provided for in Regulation (EC) No 883/2004 should be able to benefit from the principles of free movement of patients, services and goods in accordance with the TFEU and with this Directive. Patients should enjoy a guarantee of assumption of the costs of that healthcare at least at the level as would be provided for the same healthcare, had it been provided in the Member State of affiliation. This should fully respect the responsibility of the Member States to determine the extent of the sickness cover available to their citizens and prevent any significant effect on the financing of the national healthcare systems.

(30) For patients, therefore, the two systems should be coherent; either this Directive applies or the Union regulations on the coordination of social security systems apply.

(31) Patients should not be deprived of the more beneficial rights guaranteed by the Union Regulations on the coordination of social security systems when the conditions are met. Therefore, any patient who requests an authorisation to receive treatment appropriate to his condition in another Member State should always be granted this authorisation under the conditions provided for in the Unions regulations when the treatment in question is among the benefits provided for by the legislation in the Member State where the patient resides and when the patient cannot be given such treatment within a time limit that is medically justifiable, taking account of his current state of health and the probable course of the condition. However, if a patient instead explicitly requests to seek treatment under the terms of this Directive, the benefits which apply to reimbursement should be limited to those which apply under this Directive. Where the patient is entitled to cross-border healthcare under both this Directive and Regulation (EC) No 883/2004, and the application of that Regulation is more advantageous to the patient, the patient's attention should be drawn to this by the Member State of affiliation.

[1] OJ L 281, 23.11.1995, p. 31.
[2] OJ L 149, 5.7.1971, p. 2.
[3] OJ L 344, 29.12.2010, p. 1.
[4] OJ L 124, 20.5.2003, p. 1.

(32) Patients should, in any event, not derive a financial advantage from the healthcare provided in another Member State and the assumption of costs should be therefore limited only to the actual costs of healthcare received.

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

(34) Member States of affiliation should give patients the right to receive at least the same benefits in another Member State as those provided for by the legislation of the Member State of affiliation. If the list of benefits does not specify precisely the treatment method applied but defines types of treatment, the Member State of affiliation should not refuse prior authorisation or reimbursement on the grounds that the treatment method is not available in its territory, but should assess if the cross-border treatment sought or received corresponds to benefits provided for in its legislation. The fact that the obligation to reimburse cross-border healthcare under this Directive is limited to such healthcare that is among the benefits to which the patient is entitled within its Member State of affiliation does not preclude Member States from reimbursing the cost of cross-border healthcare beyond those limits. Member States are free, for example, to reimburse extra costs, such as accommodation and travel costs, or extra costs incurred by persons with disabilities even where those costs are not reimbursed in the case of healthcare provided in their territory.

(35) This Directive should not provide either for the transfer of social security entitlements between Member States or other coordination of social security systems. The sole objective of the provisions regarding prior authorisation and reimbursement of healthcare provided in another Member State should be to enable freedom to provide healthcare for patients and to remove unjustified obstacles to that fundamental freedom within the patient's Member State of affiliation. Consequently this Directive should fully respect the differences in national healthcare systems and the Member States' responsibilities for the organisation and delivery of health services and medical care.

(36) This Directive should provide for the right for a patient to receive any medicinal product authorised for marketing in the Member State of treatment, even if the medicinal product is not authorised for marketing in the Member State of affiliation, as it is an indispensable part of obtaining effective treatment in another Member State. Nothing should oblige a Member State of affiliation to reimburse an insured person for a medicinal product prescribed in the Member State of treatment, where that medicinal product is not among the benefits provided to that insured person by the statutory social security system or national health system in the Member State of affiliation.

(37) Member States may maintain general conditions, criteria for eligibility and regulatory and administrative formalities for receipt of healthcare and reimbursement of healthcare costs, such as the requirement to consult a general practitioner before consulting a specialist or before receiving hospital care, also in relation to patients seeking healthcare in another Member State, provided that such conditions are necessary, proportionate to the aim, not discretionary or discriminatory. This may include an assessment by a health professional or healthcare administrator providing services for the statutory social security system or national health system of the Member State of affiliation, such as the general practitioner or primary care practitioner with whom the patient is registered, if this is necessary for determining the individual patient's entitlement to healthcare. It is thus appropriate to require that these general conditions, criteria and formalities should be applied in an objective, transparent and non-discriminatory way and should be known in advance, based primarily on medical considerations, and that they should not impose any additional burden on patients seeking healthcare in another Member State in comparison with patients being treated in their Member State of affiliation, and that decisions should be made as quickly as possible. This should be without prejudice to the rights of the Member States to lay down criteria or conditions for prior authorisation in the case of patients seeking healthcare in their Member State of affiliation.

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

(39) Patient flows between Member States are limited and expected to remain so, as the vast majority of patients in the Union receive healthcare in their own country and prefer to do so. However, in certain circumstances

patients may seek some forms of healthcare in another Member State. Examples include highly specialised care or healthcare provided in frontier areas where the nearest appropriate facility is on the other side of the border. Furthermore, some patients wish to be treated abroad in order to be close to their family members who are residing in another Member State, or in order to have access to a different method of treatment than that provided in the Member State of affiliation or because they believe that they will receive better quality healthcare in another Member State.

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

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

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

(43) The criteria attached to the grant of prior authorisation should be justified in the light of the overriding reasons of general interest capable of justifying obstacles to the free movement of healthcare, such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources. The Court of Justice has identified several potential considerations: the risk of seriously undermining the financial balance of a social security system, the objective of maintaining on grounds of public health a balanced medical and hospital service open to all and the objective of maintaining treatment capacity or medical competence on national territory, essential for the public health, and even the survival of the population. It is also important to take into consideration the general principle of ensuring the safety of the patient, in a sector well known for information asymmetry, when managing a prior authorisation system. Conversely, the refusal to grant prior authorisation may not be based on the ground that there are waiting lists on national territory intended to enable the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out an objective medical assessment.

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

(45) Where the patient is entitled to healthcare and that healthcare cannot be provided within a time limit which is medically justifiable, the Member State of affiliation should in principle be obliged to grant prior authorisation. However, in certain circumstances, cross-border healthcare may expose the patient or the general public to a risk which overrides the interest of the patient to receive the cross-border healthcare sought. In such instances, the Member State of affiliation should be able to refuse the request for prior authorisation, in which case the Member State of affiliation should direct the patient towards alternative solutions.

(46) In any event, if a Member State decides to establish a system of prior authorisation for assumption of costs of hospital or specialised care provided in another Member State in accordance with the provision of this Directive, the costs of such care provided in another Member State should also be reimbursed by the Member State of affiliation up to the level of costs that would have been assumed had the same healthcare been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received. However, when the conditions set out in Regulation (EEC) No 1408/71 or Regulation (EC) No 883/2004 are fulfilled, the authorisation should be granted and the benefits provided in accordance with Regulation (EC) No 883/2004 unless otherwise requested by the patient. This should apply in particular in instances where the authorisation is granted after an administrative or judicial review of the request and the person concerned has received the treatment in another Member State. In that event, Articles 7 and 8 of this Directive should not apply. This is in line with the case-law of the Court of Justice which has specified that patients who were refused prior authorisation on grounds that were subsequently held to be unfounded, are entitled to have the cost of the treatment obtained in another Member State reimbursed in full according to the provisions of the legislation in the Member State of treatment.

(47) Procedures regarding cross-border healthcare established by the Member States should give patients guarantees of objectivity, non-discrimination and transparency, in such a way as to ensure that decisions by national authorities are made in a timely manner and with due care and regard for both those overall principles and the individual circumstances of each case. This should also apply to the actual reimbursement of costs of healthcare incurred in another Member State after the patient has received treatment. It is appropriate that, under normal circumstances, patients be entitled to receive decisions regarding cross-border healthcare within a reasonable period of time. However, that period should be shortened where warranted by the urgency of the treatment in question.

(48) Appropriate information on all essential aspects of cross-border healthcare is necessary in order to enable patients to exercise their rights on cross-border healthcare in practice. For cross-border healthcare, one of the mechanisms for providing such information is to establish national contact points within each Member State. Information that has to be provided compulsorily to patients should be specified. However, the national contact points may provide more information voluntarily and also with the support of the Commission. Information should be provided by national contact points to patients in any of the official languages of the Member State in which the contact points are situated. Information may be provided in any other language.

(49) The Member States should decide on the form and number of their national contact points. Such national contact points may also be incorporated in, or build on, activities of existing information centres provided that it is clearly indicated that they are also national contact points for cross-border healthcare. National contact points should be established in an efficient and transparent way and they should be able to consult with patient organisations, healthcare insurers and healthcare providers. The national contact points should have appropriate facilities to provide information on the main aspects of cross-border healthcare. The Commission should work together with the Member States in order to facilitate cooperation regarding national contact points for cross-border healthcare, including making relevant information available at Union level. The existence of national contact points should not preclude Member States from establishing other linked contact points at regional or local level, reflecting the specific organisation of their healthcare system.

(50) Member States should facilitate cooperation between healthcare providers, purchasers and regulators of different Member States at national, regional or local level in order to ensure safe, high-quality and efficient cross-border healthcare. This could be of particular importance in border regions, where cross-border provision of services may be the most efficient way of organising health services for the local population, but where achieving such cross-border provision on a sustained basis requires cooperation between the health systems of different Member States. Such cooperation may concern joint planning, mutual recognition or adaptation of procedures or standards, interoperability of respective national information and communication technology (hereinafter 'ICT') systems, practical mechanisms to ensure continuity of care or practical facilitating of cross-border provision of healthcare by health professionals on a temporary or occasional basis. Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications [1] stipulates that free provision of services of a temporary or occasional nature, including services provided by health professionals, in another Member State is not, subject to specific provisions of Union law, to be restricted for

[1] OJ L 255, 30.9.2005, p. 22.

any reason relating to professional qualifications. This Directive should be without prejudice to Directive 2005/36/EC.

(51) The Commission should encourage cooperation between Member States in the areas set out in Chapter IV of this Directive and may, in accordance with Article 168(2) TFEU, take, in close contact with the Member States, any useful initiative to facilitate and promote such cooperation. In that context, the Commission should encourage cooperation in cross-border healthcare provision at regional and local level, particularly by identifying major obstacles to collaboration between healthcare providers in border regions, and by making recommendations and disseminating information and best practices on how to overcome such obstacles.

(52) The Member State of affiliation may need to receive confirmation that the cross-border healthcare will be, or has been, delivered by a legally practising health professional. It is therefore appropriate to ensure that information on the right to practise contained in the national or local registers of health professionals, if established in the Member State of treatment, are, upon request, made available to the authorities of the Member State of affiliation.

(53) Where medicinal products are authorised within a Member State and have been prescribed in that Member State by a member of a regulated health profession within the meaning of Directive 2005/36/EC for an individual named patient, it should, in principle, be possible for such prescriptions to be medically recognised and for the medicinal products to be dispensed in another Member State in which the medicinal products are authorised. The removal of regulatory and administrative barriers to such recognition should be without prejudice to the need for appropriate agreement of the patient's treating physician or pharmacist in every individual case, if this is warranted by protection of human health and is necessary and proportionate to that objective. The recognition of prescriptions from other Member States should not affect any professional or ethical duty that would require pharmacists to refuse to dispense the prescription. Such medical recognition should also be without prejudice to the decision of the Member State of affiliation regarding the inclusion of such medicinal products among the benefits covered by the social security system of affiliation. It should further be noted that the reimbursement of medicinal products is not affected by the rules on mutual recognition of prescriptions, but covered by the general rules on reimbursement of cross-border healthcare in Chapter III of this Directive. The implementation of the principle of recognition should be facilitated by the adoption of measures necessary for safeguarding the safety of a patient, and avoiding the misuse or confusion of medicinal products. These measures should include the adoption of a non-exhaustive list of elements to be included in prescriptions. Nothing should prevent Member States from having further elements in their prescriptions, as long as this does not prevent prescriptions from other Member States that contain the common list of elements from being recognised. The recognition of prescriptions should also apply for medical devices that are legally placed on the market in the Member State where the device will be dispensed.

(54) The Commission should support the continued development of European reference networks between healthcare providers and centres of expertise in the Member States. European reference networks can improve the access to diagnosis and the provision of high-quality healthcare to all patients who have conditions requiring a particular concentration of resources or expertise, and could also be focal points for medical training and research, information dissemination and evaluation, especially for rare diseases. This Directive should therefore give incentives to Member States to reinforce the continued development of European reference networks. European reference networks are based on the voluntary participation of their members, but the Commission should develop criteria and conditions that the networks should be required to fulfil in order to receive support from the Commission.

(55) Rare diseases are those that meet a prevalence threshold of not more than five affected persons per 10 000, in line with Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products [1], and they are all serious, chronic and often life threatening. Some patients affected by rare diseases face difficulties in their quest for a diagnosis and treatment to improve their quality of life and to increase their life expectancy, difficulties which were also recognised by the Council Recommendation of 8 June 2009 on an action in the field of rare diseases [2].

(56) Technological developments in cross-border provision of healthcare through the use of ICTs may result in the exercise of supervisory responsibilities by Member States being unclear, and can thus hinder the free movement of healthcare and give rise to possible additional risks to health protection. Widely different and incompatible formats and standards are used for provision of healthcare using ICTs throughout the Union, creating both obstacles to this mode of cross-border healthcare provision and possible risks to health protection. It is therefore necessary for Member States to aim at interoperability of ICT systems. The deployment of health ICT systems, however, is entirely a national competence. This Directive therefore should recognise the importance of the work on interoperability and respect the division of competences by providing for the Commission and Member States to work together on developing measures which are not legally binding but provide additional tools that are available to Member States to facilitate greater interoperability of

[1] OJ L 18, 22.1.2000, p. 1.
[2] OJ C 151, 3.7.2009, p. 7.

ICT systems in the healthcare field and to support patient access to eHealth applications, whenever Member States decide to introduce them.

(57) The interoperability of eHealth solutions should be achieved whilst respecting national regulations on the provision of healthcare services adopted in order to protect the patient, including legislation on Internet pharmacies, in particular national bans on mail order of prescription-only medicinal products to the extent that they are compatible with the case-law of the Court of Justice and Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts ([1]) and Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ([2]).

(58) The constant progress of medical science and health technologies presents both opportunities and challenges to the health systems of the Member States. Cooperation in the evaluation of new health technologies can support Member States through economies of scale and avoid duplication of effort, and provide a better evidence base for optimal use of new technologies to ensure safe, high-quality and efficient healthcare. Such cooperation requires sustained structures involving all the relevant authorities of the Member States, building on existing pilot projects and consultation of a wide range of stakeholders. This Directive should therefore provide a basis for continued Union support for such cooperation.

(59) According to Article 291 TFEU, rules and general principles concerning mechanisms for the control by Member States of the Commission's exercise of implementing powers are to be laid down in advance by a regulation adopted in accordance with the ordinary legislative procedure. Pending the adoption of that new Regulation, Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ([3]) continues to apply, with the exception of the regulatory procedure with scrutiny, which is not applicable.

(60) The Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU in respect of measures that would exclude specific categories of medicinal products or medical devices from the recognition of prescriptions, as provided for in this Directive. In order to identify the reference networks which should benefit from support by the Commission, the Commission should also be empowered to adopt delegated acts in respect of the criteria and conditions that European reference networks have to fulfil.

(61) It is of particular importance that, when empowered to adopt delegated acts in accordance with Article 290 TFEU, the Commission carry out appropriate consultations during its preparatory work, including at expert level.

(62) In accordance with point 34 of the Interinstitutional Agreement on better law-making ([4]), Member States are encouraged to draw up, for themselves and in the interests of the Union, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public.

(63) The European Data Protection Supervisor has also delivered his opinion on the proposal for this Directive ([5]).

(64) Since the objective of this Directive, namely providing rules for facilitating the access to safe and high quality cross-border healthcare in the Union, cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter and scope

1. This Directive provides rules for facilitating the access to safe and high-quality cross-border healthcare and promotes cooperation on healthcare between Member States, in full respect of national competencies in organising and delivering healthcare. This Directive also aims at clarifying its relationship with the existing framework on the coordination of social security systems, Regulation (EC) No 883/2004, with a view to application of patients' rights.

([1]) OJ L 144, 4.6.1997, p. 19.
([2]) OJ L 178, 17.7.2000, p. 1.
([3]) OJ L 184, 17.7.1999, p. 23.
([4]) OJ C 321, 31.12.2003, p. 1.
([5]) OJ C 128, 6.6.2009, p. 20.

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

3. This Directive shall not apply to:

(a) services in the field of long-term care the purpose of which is to support people in need of assistance in carrying out routine, everyday tasks;

(b) allocation of and access to organs for the purpose of organ transplants;

(c) with the exception of Chapter IV, public vaccination programmes against infectious diseases which are exclusively aimed at protecting the health of the population on the territory of a Member State and which are subject to specific planning and implementation measures.

4. This Directive shall not affect laws and regulations in Member States relating to the organisation and financing of healthcare in situations not related to cross-border healthcare. In particular, nothing in this Directive obliges a Member State to reimburse costs of healthcare provided by healthcare providers established on its own territory if those providers are not part of the social security system or public health system of that Member State.

Article 2

Relationship with other Union provisions

This Directive shall apply without prejudice to:

(a) Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems ([1]);

(b) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices ([2]), Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ([3]) and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices ([4]);

(c) Directive 95/46/EC and Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector ([5]);

(d) Directive 96/71/EC of the European Parliament and of the Council of 16 December 1996 concerning the posting of workers in the framework of the provision of services ([6]);

(e) Directive 2000/31/EC;

(f) Council Directive 2000/43/EC of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin ([7]);

(g) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use ([8]);

(h) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ([9]);

(i) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components ([10]);

(j) Regulation (EC) No 859/2003;

(k) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells ([11]);

(l) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency ([12]);

(m) Regulation (EC) No 883/2004 and Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems ([13]);

(n) Directive 2005/36/EC;

(o) Regulation (EC) No 1082/2006 of the European Parliament and of the Council of 5 July 2006 on a European grouping of territorial cooperation (EGTC) ([14]);

([1]) OJ L 40, 11.2.1989, p. 8.
([2]) OJ L 189, 20.7.1990, p. 17.
([3]) OJ L 169, 12.7.1993, p. 1.
([4]) OJ L 331, 7.12.1998, p. 1.
([5]) OJ L 201, 31.7.2002, p. 37.
([6]) OJ L 18, 21.1.1997, p. 1.
([7]) OJ L 180, 19.7.2000, p. 22.
([8]) OJ L 121, 1.5.2001, p. 34.
([9]) OJ L 311, 28.11.2001, p. 67.
([10]) OJ L 33, 8.2.2003, p. 30.
([11]) OJ L 102, 7.4.2004, p. 48.
([12]) OJ L 136, 30.4.2004, p. 1.
([13]) OJ L 284, 30.10.2009, p. 1.
([14]) OJ L 210, 31.7.2006, p. 19.

(p) Regulation (EC) No 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work [1];

(q) Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I) [2], Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II) [3] and other Union rules on private international law, in particular rules related to court jurisdiction and the applicable law;

(r) Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation [4];

(s) Regulation (EU) No 1231/2010.

Article 3

Definitions

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

(a) 'healthcare' means health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices;

(b) 'insured person' means:

(i) persons, including members of their families and their survivors, who are covered by Article 2 of Regulation (EC) No 883/2004 and who are insured persons within the meaning of Article 1(c) of that Regulation; and

(ii) nationals of a third country who are covered by Regulation (EC) No 859/2003 or Regulation (EU) No 1231/2010, or who satisfy the conditions of the legislation of the Member State of affiliation for entitlement to benefits;

(c) 'Member State of affiliation' means:

(i) for persons referred to in point (b)(i), the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment outside the Member State of residence according to Regulations (EC) No 883/2004 and (EC) No 987/2009;

(ii) for persons referred to in point (b)(ii), the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment in another Member State according to Regulation (EC) No 859/2003 or Regulation (EU) No 1231/2010. If no Member State is competent according to those Regulations, the Member State of affiliation shall be the Member State where the person is insured or has the rights to sickness benefits according to the legislation of that Member State;

(d) 'Member State of treatment' means the Member State on whose territory healthcare is actually provided to the patient. In the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established;

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

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

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

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

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

(j) 'medical device' means a medical device as defined by Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC;

(k) 'prescription' means a prescription for a medicinal product or for a medical device issued by a member of a regulated health profession within the meaning of Article 3(1)(a) of Directive 2005/36/EC who is legally entitled to do so in the Member State in which the prescription is issued;

[1] OJ L 354, 31.12.2008, p. 70.
[2] OJ L 177, 4.7.2008, p. 6.
[3] OJ L 199, 31.7.2007, p. 40.
[4] OJ L 207, 6.8.2010, p. 14.

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

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

CHAPTER II

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

Article 4

Responsibilities of the Member State of treatment

1. Taking into account the principles of universality, access to good quality care, equity and solidarity, cross-border healthcare shall be provided in accordance with:

(a) the legislation of the Member State of treatment;

(b) standards and guidelines on quality and safety laid down by the Member State of treatment; and

(c) Union legislation on safety standards.

2. The Member State of treatment shall ensure that:

(a) patients receive from the national contact point referred to in Article 6, upon request, relevant information on the standards and guidelines referred to in paragraph 1(b) of this Article, including provisions on supervision and assessment of healthcare providers, information on which healthcare providers are subject to these standards and guidelines and information on the accessibility of hospitals for persons with disabilities;

(b) healthcare providers provide relevant information to help individual patients to make an informed choice, including on treatment options, on the availability, quality and safety of the healthcare they provide in the Member State of treatment and that they also provide clear invoices and clear information on prices, as well as on their authorisation or registration status, their insurance cover or other means of personal or collective protection with regard to professional liability. To the extent that healthcare providers already provide patients resident in the Member State of treatment with relevant information on these subjects, this Directive does not oblige healthcare providers to provide more extensive information to patients from other Member States;

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

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

(e) the fundamental right to privacy with respect to the processing of personal data is protected in conformity with national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC;

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

3. The principle of non-discrimination with regard to nationality shall be applied to patients from other Member States.

This shall be without prejudice to the possibility for the Member State of treatment, where it is justified by overriding reasons of general interest, such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources, to adopt measures regarding access to treatment aimed at fulfilling its fundamental responsibility to ensure sufficient and permanent access to healthcare within its territory. Such measures shall be limited to what is necessary and proportionate and may not constitute a means of arbitrary discrimination and shall be made publicly available in advance.

4. Member States shall ensure that the healthcare providers on their territory apply the same scale of fees for healthcare for patients from other Member States, as for domestic patients in a comparable medical situation, or that they charge a price calculated according to objective, non-discriminatory criteria if there is no comparable price for domestic patients.

This paragraph shall be without prejudice to national legislation which allows healthcare providers to set their own prices, provided that they do not discriminate against patients from other Member States.

5. This Directive shall not affect laws and regulations in Member States on the use of languages. Member States may choose to deliver information in other languages than those which are official languages in the Member State concerned.

Article 5

Responsibilities of the Member State of affiliation

The Member State of affiliation shall ensure that:

(a) the cost of cross-border healthcare is reimbursed in accordance with Chapter III;

(b) there are mechanisms in place to provide patients on request with information on their rights and entitlements in that Member State relating to receiving cross-border healthcare, in particular as regards the terms and conditions for reimbursement of costs in accordance with Article 7(6) and procedures for accessing and determining those entitlements and for appeal and redress if patients consider that their rights have not been respected, in accordance with Article 9. In information about cross-border healthcare, a clear distinction shall be made between the rights which patients have by virtue of this Directive and rights arising from Regulation (EC) No 883/2004;

(c) where a patient has received cross-border healthcare and where medical follow-up proves necessary, the same medical follow-up is available as would have been if that healthcare had been provided on its territory;

(d) patients who seek to receive or do receive cross-border healthcare have remote access to or have at least a copy of their medical records, in conformity with, and subject to, national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.

Article 6

National contact points for cross-border healthcare

1. Each Member State shall designate one or more national contact points for cross-border healthcare and communicate their names and contact details to the Commission. The Commission and the Member States shall make this information publicly available. Member States shall ensure that the national contact points consult with patient organisations, healthcare providers and healthcare insurers.

2. National contact points shall facilitate the exchange of information referred to in paragraph 3 and shall cooperate closely with each other and with the Commission. National contact points shall provide patients on request with contact details of national contact points in other Member States.

3. In order to enable patients to make use of their rights in relation to cross-border healthcare, national contact points in the Member State of treatment shall provide them with information concerning healthcare providers, including, on request, information on a specific provider's right to provide services or any restrictions on its practice, information referred to in Article 4(2)(a), as well as information on patients' rights, complaints procedures and mechanisms for seeking remedies, according to the legislation of that Member State, as well as the legal and administrative options available to settle disputes, including in the event of harm arising from cross-border healthcare.

4. National contact points in the Member State of affiliation shall provide patients and health professionals with the information referred to in Article 5(b).

5. The information referred to in this Article shall be easily accessible and shall be made available by electronic means and in formats accessible to people with disabilities, as appropriate.

CHAPTER III

REIMBURSEMENT OF COSTS OF CROSS-BORDER HEALTHCARE

Article 7

General principles for reimbursement of costs

1. Without prejudice to Regulation (EC) No 883/2004 and subject to the provisions of Articles 8 and 9, the Member State of affiliation shall ensure the costs incurred by an insured person who receives cross-border healthcare are reimbursed, if the healthcare in question is among the benefits to which the insured person is entitled in the Member State of affiliation.

2. By way of derogation from paragraph 1:

(a) if a Member State is listed in Annex IV to Regulation (EC) No 883/2004 and in compliance with that Regulation has recognised the rights to sickness benefits for pensioners and the members of their families, being resident in a different Member State, it shall provide them healthcare under this Directive at its own expense when they stay on its territory, in accordance with its legislation, as though the persons concerned were residents in the Member State listed in that Annex;

(b) if the healthcare provided in accordance with this Directive is not subject to prior authorisation, is not provided in accordance with Chapter 1 of Title III of the Regulation (EC) No 883/2004, and is provided in the territory of the Member State that according to that Regulation and Regulation (EC) No 987/2009 is, in the end, responsible for reimbursement of the costs, the costs shall be assumed by that Member State. That Member State may assume the costs of the healthcare in accordance with the terms, conditions, criteria for eligibility and regulatory and administrative formalities that it has established, provided that these are compatible with the TFEU.

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

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

Where the full cost of cross-border healthcare exceeds the level of costs that would have been assumed had the healthcare been provided in its territory the Member State of affiliation may nevertheless decide to reimburse the full cost.

The Member State of affiliation may decide to reimburse other related costs, such as accommodation and travel costs, or extra costs which persons with disabilities might incur due to one or more disabilities when receiving cross-border healthcare, in accordance with national legislation and on the condition that there be sufficient documentation setting out these costs.

5. Member States may adopt provisions in accordance with the TFEU aimed at ensuring that patients enjoy the same rights when receiving cross-border healthcare as they would have enjoyed if they had received healthcare in a comparable situation in the Member State of affiliation.

6. For the purposes of paragraph 4, Member States shall have a transparent mechanism for calculation of costs of cross-border healthcare that are to be reimbursed to the insured person by the Member State of affiliation. This mechanism shall be based on objective, non-discriminatory criteria known in advance and applied at the relevant (local, regional or national) administrative level.

7. The Member State of affiliation may impose on an insured person seeking reimbursement of the costs of cross-border healthcare, including healthcare received through means of telemedicine, the same conditions, criteria of eligibility and regulatory and administrative formalities, whether set at a local, regional or national level, as it would impose if this healthcare were provided in its territory. This may include an assessment by a health professional or healthcare administrator providing services for the statutory social security system or national health system of the Member State of affiliation, such as the general practitioner or primary care practitioner with whom the patient is registered, if this is necessary for determining the individual patient's entitlement to healthcare. However, no conditions, criteria of eligibility and regulatory and administrative formalities imposed according to this paragraph may be discriminatory or constitute an obstacle to the free movement of patients, services or goods, unless it is objectively justified by planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources.

8. The Member State of affiliation shall not make the reimbursement of costs of cross-border healthcare subject to prior authorisation except in the cases set out in Article 8.

9. The Member State of affiliation may limit the application of the rules on reimbursement for cross-border healthcare based on overriding reasons of general interest, such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources.

10. Notwithstanding paragraph 9, Member States shall ensure that the cross-border healthcare for which a prior authorisation has been granted is reimbursed in accordance with the authorisation.

11. The decision to limit the application of this Article pursuant to paragraph 9 shall be restricted to what is necessary and proportionate, and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of goods, persons or services. Member States shall notify the Commission of any decisions to limit reimbursement on the grounds stated in paragraph 9.

Article 8

Healthcare that may be subject to prior authorisation

1. The Member State of affiliation may provide for a system of prior authorisation for reimbursement of costs of cross-border healthcare, in accordance with this Article and Article 9. The system of prior authorisation, including the criteria and the application of those criteria, and individual decisions of refusal to grant prior authorisation, shall be restricted to what is necessary and proportionate to the objective to be achieved, and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of patients.

2. Healthcare that may be subject to prior authorisation shall be limited to healthcare which:

(a) is made subject to planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources and:

(i) involves overnight hospital accommodation of the patient in question for at least one night; or

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

(b) involves treatments presenting a particular risk for the patient or the population; or

(c) is provided by a healthcare provider that, on a case-by-case basis, could give rise to serious and specific concerns relating to the quality or safety of the care, with the exception of healthcare which is subject to Union legislation ensuring a minimum level of safety and quality throughout the Union.

Member States shall notify the categories of healthcare referred to in point (a) to the Commission.

3. With regard to requests for prior authorisation made by an insured person with a view to receiving cross-border healthcare, the Member State of affiliation shall ascertain whether the conditions laid down in Regulation (EC) No 883/2004 have been met. Where those conditions are met, the prior authorisation shall be granted pursuant to that Regulation unless the patient requests otherwise.

4. When a patient affected, or suspected of being affected, by a rare disease applies for prior authorisation, a clinical evaluation may be carried out by experts in that field. If no experts can be found within the Member State of affiliation or if the expert's opinion is inconclusive, the Member State of affiliation may request scientific advice.

5. Without prejudice to points (a) to (c) of paragraph 6, the Member State of affiliation may not refuse to grant prior authorisation when the patient is entitled to the healthcare in question in accordance with Article 7, and when this healthcare cannot be provided on its territory within a time limit which is medically justifiable, based on an objective medical assessment of the patient's medical condition, the history and probable course of the patient's illness, the degree of the patient's pain and/or the nature of the patient's disability at the time when the request for authorisation was made or renewed.

6. The Member State of affiliation may refuse to grant prior authorisation for the following reasons:

(a) the patient will, according to a clinical evaluation, be exposed with reasonable certainty to a patient-safety risk that cannot be regarded as acceptable, taking into account the potential benefit for the patient of the sought cross-border healthcare;

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

(c) this healthcare is to be provided by a healthcare provider that raises serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety, including provisions on supervision, whether these standards and guidelines are laid down by laws and regulations or through accreditation systems established by the Member State of treatment;

(d) this healthcare can be provided on its territory within a time limit which is medically justifiable, taking into account the current state of health and the probable course of the illness of each patient concerned.

7. The Member State of affiliation shall make publicly available which healthcare is subject to prior authorisation for the purposes of this Directive, as well as all relevant information on the system of prior authorisation.

Article 9

Administrative procedures regarding cross-border healthcare

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

2. Any administrative procedure of the kind referred to in paragraph 1 shall be easily accessible and information relating to such a procedure shall be made publicly available at the appropriate level. Such a procedure shall be capable of ensuring that requests are dealt with objectively and impartially.

3. Member States shall set out reasonable periods of time within which requests for cross-border healthcare must be dealt with and make them public in advance. When considering a request for cross-border healthcare, Member States shall take into account:

(a) the specific medical condition;

(b) the urgency and individual circumstances.

4. Member States shall ensure that individual decisions regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State are properly reasoned and subject, on a case-by-case basis, to review and are capable of being challenged in judicial proceedings, which include provision for interim measures.

5. This Directive is without prejudice to Member States' right to offer patients a voluntary system of prior notification whereby, in return for such notification, the patient receives a written confirmation of the amount to be reimbursed on the basis of an estimate. This estimate shall take into account the patient's clinical case, specifying the medical procedures likely to apply.

Member States may choose to apply the mechanisms of financial compensation between the competent institutions as provided for by Regulation (EC) No 883/2004. Where a Member State of affiliation does not apply such mechanisms, it shall ensure that patients receive reimbursement without undue delay.

CHAPTER IV

COOPERATION IN HEALTHCARE

Article 10

Mutual assistance and cooperation

1. Member States shall render such mutual assistance as is necessary for the implementation of this Directive, including cooperation on standards and guidelines on quality and safety and the exchange of information, especially between their national contact points in accordance with Article 6, including on provisions on supervision and mutual assistance to clarify the content of invoices.

2. Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level as well as through ICT and other forms of cross-border cooperation.

3. The Commission shall encourage Member States, particularly neighbouring countries, to conclude agreements among themselves. The Commission shall also encourage the Member States to cooperate in cross-border healthcare provision in border regions.

4. Member States of treatment shall ensure that information on the right to practise of health professionals listed in national or local registers established on their territory is, upon request, made available to the authorities of other Member States, for the purpose of cross-border healthcare, in accordance with Chapters II and III and with national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC, and the principle of presumption of innocence. The exchange of information shall take place via the Internal Market Information system established pursuant to Commission Decision 2008/49/EC of 12 December 2007 concerning the implementation of the Internal Market Information System (IMI) as regards the protection of personal data [1].

Article 11

Recognition of prescriptions issued in another Member State

1. If a medicinal product is authorised to be marketed on their territory, in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004, Member States shall ensure that prescriptions issued for such a product in another Member State for a named patient can be dispensed on their territory in compliance with their national legislation in force, and that any restrictions on recognition of individual prescriptions are prohibited unless such restrictions are:

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

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

[1] OJ L 13, 16.1.2008, p. 18.

The recognition of such prescriptions shall not affect national rules governing prescribing and dispensing, if those rules are compatible with Union law, including generic or other substitution. The recognition of prescriptions shall not affect the rules on reimbursement of medicinal products. Reimbursement of costs of medicinal products is covered by Chapter III of this Directive.

In particular, the recognition of prescriptions shall not affect a pharmacist's right, by virtue of national rules, to refuse, for ethical reasons, to dispense a product that was prescribed in another Member State, where the pharmacist would have the right to refuse to dispense, had the prescription been issued in the Member State of affiliation.

The Member State of affiliation shall take all necessary measures, in addition to the recognition of the prescription, in order to ensure continuity of treatment in cases where a prescription is issued in the Member State of treatment for medicinal products or medical devices available in the Member State of affiliation and where dispensing is sought in the Member State of affiliation.

This paragraph shall also apply to medical devices that are legally placed on the market in the respective Member State.

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

(a) measures enabling a health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by a member of a regulated health profession who is legally entitled to do so through developing a non-exhaustive list of elements to be included in the prescriptions and which must be clearly identifiable in all prescription formats, including elements to facilitate, if needed, contact between the prescribing party and the dispensing party in order to contribute to a complete understanding of the treatment, in due respect of data protection;

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

(c) measures to facilitate the correct identification of medicinal products or medical devices prescribed in one Member State and dispensed in another, including measures to address patient safety concerns in relation to their substitution in cross border healthcare where the legislation of the dispensing Member State permits such substitution. The Commission shall consider, inter alia, using the International Non-proprietary Name and the dosage of medicinal products;

(d) measures to facilitate the comprehensibility of the information to patients concerning the prescription and the instructions included on the use of the product, including an indication of active substance and dosage.

Measures referred in point (a) shall be adopted by the Commission no later than 25 December 2012 and measures in points (c) and (d) shall be adopted by the Commission no later than 25 October 2012.

3. The measures and guidelines referred to in points (a) to (d) of paragraph 2 shall be adopted in accordance with the regulatory procedure referred to in Article 16(2).

4. In adopting measures or guidelines under paragraph 2, the Commission shall have regard to the proportionality of any costs of compliance with, as well as the likely benefits of, the measures or guidelines.

5. For the purpose of paragraph 1, the Commission shall also adopt, by means of delegated acts in accordance with Article 17 and subject to the conditions of Articles 18 and 19 and no later than 25 October 2012 measures to exclude specific categories of medicinal products or medical devices from the recognition of prescriptions provided for under this Article, where necessary in order to safeguard public health.

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

Article 12

European reference networks

1. The Commission shall support Member States in the development of European reference networks between healthcare providers and centres of expertise in the Member States, in particular in the area of rare diseases. The networks shall be based on voluntary participation by its members, which shall participate and contribute to the networks' activities in accordance with the legislation of the Member State where the members are established and shall at all times be open to new healthcare providers which might wish to join them, provided that such healthcare providers fulfil all the required conditions and criteria referred to in paragraph 4.

2. European reference networks shall have at least three of the following objectives:

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

(b) to contribute to the pooling of knowledge regarding sickness prevention;

(c) to facilitate improvements in diagnosis and the delivery of high-quality, accessible and cost-effective healthcare for all patients with a medical condition requiring a particular concentration of expertise in medical domains where expertise is rare;

(d) to maximise the cost-effective use of resources by concentrating them where appropriate;

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

(f) to facilitate mobility of expertise, virtually or physically, and to develop, share and spread information, knowledge and best practice and to foster developments of the diagnosis and treatment of rare diseases, within and outside the networks;

(g) to encourage the development of quality and safety benchmarks and to help develop and spread best practice within and outside the network;

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

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

(a) by connecting appropriate healthcare providers and centres of expertise throughout their national territory and ensuring the dissemination of information towards appropriate healthcare providers and centres of expertise throughout their national territory;

(b) by fostering the participation of healthcare providers and centres of expertise in the European reference networks.

4. For the purposes of paragraph 1, the Commission shall:

(a) adopt a list of specific criteria and conditions that the European reference networks must fulfil and the conditions and criteria required from healthcare providers wishing to join the European reference network. These criteria and conditions shall ensure, inter alia, that European reference networks:

(i) have knowledge and expertise to diagnose, follow-up and manage patients with evidence of good outcomes, as far as applicable;

(ii) follow a multi-disciplinary approach;

(iii) offer a high level of expertise and have the capacity to produce good practice guidelines and to implement outcome measures and quality control;

(iv) make a contribution to research;

(v) organise teaching and training activities; and

(vi) collaborate closely with other centres of expertise and networks at national and international level;

(b) develop and publish criteria for establishing and evaluating European reference networks;

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

5. The Commission shall adopt the measures referred to in paragraph 4(a) by means of delegated acts in accordance with Article 17 and subject to the conditions of Articles 18 and 19. The measures referred to in points (b) and (c) of paragraph 4 shall be adopted in accordance with the regulatory procedure referred to in Article 16(2).

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

Article 13

Rare diseases

The Commission shall support Member States in cooperating in the development of diagnosis and treatment capacity in particular by aiming to:

(a) make health professionals aware of the tools available to them at Union level to assist them in the correct diagnosis of rare diseases, in particular the Orphanet database, and the European reference networks;

(b) make patients, health professionals and those bodies responsible for the funding of healthcare aware of the possibilities offered by Regulation (EC) No 883/2004 for referral of patients with rare diseases to other Member States even for diagnosis and treatments which are not available in the Member State of affiliation.

Article 14

eHealth

1. The Union shall support and facilitate cooperation and the exchange of information among Member States working within a voluntary network connecting national authorities responsible for eHealth designated by the Member States.

2. The objectives of the eHealth network shall be to:

(a) work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare;

(b) draw up guidelines on:

(i) a non-exhaustive list of data that are to be included in patients' summaries and that can be shared between health professionals to enable continuity of care and patient safety across borders; and

(ii) effective methods for enabling the use of medical information for public health and research;

(c) support Member States in developing common identification and authentication measures to facilitate transferability of data in cross-border healthcare.

The objectives referred to in points (b) and (c) shall be pursued in due observance of the principles of data protection as set out, in particular, in Directives 95/46/EC and 2002/58/EC.

3. The Commission shall, in accordance with the regulatory procedure referred to in Article 16(2), adopt the necessary measures for the establishment, management and transparent functioning of this network.

Article 15

Cooperation on health technology assessment

1. The Union shall support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or bodies responsible for health technology assessment designated by the Member States. The Member States shall communicate their names and contact details to the Commission. The members of such a health technology assessment network shall participate in, and contribute to, the network's activities in accordance with the legislation of the Member State where they are established. That network shall be based on the principle of good governance including transparency, objectivity, independence of expertise, fairness of procedure and appropriate stakeholder consultations.

2. The objectives of the health technology assessment network shall be to:

(a) support cooperation between national authorities or bodies;

(b) support Member States in the provision of objective, reliable, timely, transparent, comparable and transferable information on the relative efficacy as well as on the short- and long-term effectiveness, when applicable, of health technologies and to enable an effective exchange of this information between the national authorities or bodies;

(c) support the analysis of the nature and type of information that can be exchanged;

(d) avoid duplication of assessments.

3. In order to fulfil the objectives set out in paragraph 2, the network on health technology assessment may receive Union aid. Aid may be granted in order to:

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

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

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

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

(e) facilitate the consultation of stakeholders on the work of the network.

4. The Commission shall, in accordance with the regulatory procedure referred to in Article 16(2), adopt the necessary measures for the establishment, management and transparent functioning of this network.

5. Arrangements for granting the aid, the conditions to which it may be subject and the amount of the aid, shall be adopted in accordance with the regulatory procedure referred to in Article 16(2). Only those authorities and bodies in the network designated as beneficiaries by the participating Member States shall be eligible for Union aid.

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

7. Measures adopted pursuant to this Article shall not interfere with Member States' competences in deciding on the implementation of health technology assessment conclusions and shall not harmonise any laws or regulations of the Member States and shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.

CHAPTER V

IMPLEMENTING AND FINAL PROVISIONS

Article 16

Committee

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

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 3 months.

Article 17

Exercise of the delegation

1. The powers to adopt delegated acts referred to in Articles 11(5) and 12(5) shall be conferred on the Commission for a period of 5 years from 24 April 2011. The Commission shall make a report in respect of the delegated powers not later than 6 months before the end of the five-year period. The delegation of powers shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 18.

2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

3. The powers to adopt delegated acts are conferred on the Commission subject to the conditions laid down in Articles 18 and 19.

Article 18

Revocation of the delegation

1. The delegation of power referred to in Articles 11(5) and 12(5) may be revoked at any time by the European Parliament or by the Council.

2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of power shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated powers which could be subject to revocation and possible reasons for a revocation.

3. The decision of revocation shall put an end to the delegation of the powers specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the *Official Journal of the European Union*.

Article 19

Objections to delegated acts

1. The European Parliament or the Council may object to the delegated act within a period of 2 months from the date of notification.

At the initiative of the European Parliament or the Council this period shall be extended by 2 months.

2. If, on expiry of the period referred to in paragraph 1, neither the European Parliament nor the Council has objected to the delegated act, it shall be published in the *Official Journal of the European Union* and shall enter into force on the date stated therein.

The delegated act may be published in the *Official Journal of the European Union* and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.

3. If the European Parliament or the Council objects to a delegated act within the period referred to in paragraph 1, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

Article 20

Reports

1. The Commission shall by 25 October 2015 and subsequently every 3 years thereafter, draw up a report on the operation of this Directive and submit it to the European Parliament and to the Council.

2. The report shall in particular include information on patient flows, financial dimensions of patient mobility, the implementation of Article 7(9) and Article 8, and on the functioning of the European reference networks and national contact points. To this end, the Commission shall conduct an assessment of the systems and practices put in place in the Member States, in the light of the requirements of this Directive and the other Union legislation relating to patient mobility.

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

3. Member States and the Commission shall have recourse to the Administrative Commission established pursuant to Article 71 of Regulation (EC) No 883/2004, in order to address the financial consequences of the application of this Directive on the Member States which have opted for reimbursement on the basis of fixed amounts, in cases covered by Articles 20(4) and 27(5) of that Regulation.

The Commission shall monitor and regularly report on the effect of Article 3(c)(i) and Article 8 of this Directive. A first report shall be presented by 25 October 2013. On the basis of these reports, the Commission shall, where appropriate, make proposals to alleviate any disproportionalities.

Article 21

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 25 October 2013. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by the Member States.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 22

Entry into force

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 23

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 9 March 2011.

For the European Parliament	*For the Council*
The President	*The President*
J. BUZEK	GYŐRI E.