The influence of the European Union in the field of emergency medical services

Maastricht University
Faculty of Health, Medicine and Life Sciences
Echt, 24-02-2017
Worseling, K.
I6046429
Master Governance and Leadership in European Public Health
1st UM Supervisor: Dr. Thomas Krafft
2nd UM Supervisor: Eva Pilot
External Supervisor: Marian Ramakers-van Kuijk
Placement institution: EMRIC office; Prins Bisschopsingel 53 Maastricht
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Abstract

Background: There currently are five policy areas where the European Union (EU) has exclusive competence to legislate. In all other policy areas, the EU shares competence with the member states or supports member state action. Healthcare, and more specifically pre-hospital emergency medical services (pre-hospital EMS) is such a policy field, where the EU does not have exclusive competence and is only allowed to support member state action. This, however, does not mean that the EU does not legislate in this field. Nevertheless, scientific studies on the exact extent to which the powers of the EU have influenced policy areas such as pre-hospital EMS remain scarce.

Methods: To investigate the extent to which the EU is involved in the field of pre-hospital EMS and the extent to which the effects of this involvement on pre-hospital EMS systems have been studied in scientific literature, a scoping study is conducted. This scoping review serves as a preliminary investigation that clarifies the range and nature of evidence base available.

Results: A total of 7 areas of influence were identified, where EU legislation has an effect on national pre-hospital EMS systems. The majority of instruments identified are legally binding and almost all aspects of national pre-hospital EMS systems are affected. In addition, 7 European Court of Justice (ECJ) cases were found, which were all related to the provision of pre-hospital EMS services and the awarding of public service contracts. The Comprehensive Economic and Trade Agreement (CETA) between the EU and Canada served as an example to show that trade agreements also have the ability to affect national pre-hospital EMS systems. Scientific literature looking at the extent to which national pre-hospital EMS systems are affected by EU legislation is scarce. A limited number of articles were found looking healthcare in general, with even less articles available focusing on pre-hospital EMS systems specifically.

Conclusion: The EU's influence on national pre-hospital EMS systems is far-reaching, even though the EU's competence in this specific policy field is limited. Their far-reaching influence can be explained by the fact that most of the identified authority instruments were concluded with the scope of affecting the single market, not pre-hospital EMS systems specifically. This gives rise to unforeseen consequences, as pre-hospital EMS systems were not evaluated specifically when designing these laws. Research looking at the effects this EU legislation has on national pre-hospital EMS systems is insufficient and lacking in many areas. It would therefore be recommendable to promote research initiatives in this area that could use this study as a starting point to identify areas of influence.

1 Introduction

The European Union (EU) as an institution has a long history, starting with the establishment of the European Coal and Steel Community (ECSC) in 1951 (Warleigh-Lack, 2009). The EU as we currently know it, has been created by the Maastricht Treaty in 1992, which has been amended by the treaty of Amsterdam in 1997, the treaty of Nice in 2001 and the treaty of Lisbon in 2007 (Warleigh-Lack, 2009). Over the years, the number of EU member states has increased, as has its power by the addition of new policy areas (Warleigh-Lack, 2009). There currently are a total of five policy areas, where the EU has exclusive competence to legislate (European Union, 2012b). In all other policy areas, the EU either shares competence with the member states or can support member state action (European Union, 2012b).

Healthcare is one of the fields where the EU does not have exclusive competence and is only allowed to *"support, coordinate or supplement the actions of the Member States"* (European Union, 2012b, p. 52). This, however, does not mean that the EU is not able to influence policy fields such as healthcare. In 1992, the Maastricht Treaty introduced a specific article on health, namely article 168 on public health (Greer et al., 2014). The powers given to the EU based on article 168 remain limited to support, coordinate or supplement Member State action, except in the field of *"substances of human origin, blood and blood derivatives",* where binding legislation is allowed (Greer et al., 2014, p. 20). Within the treaty there are, nevertheless, other provisions that provide the EU with more power and can be used as a basis to interfere in the field of healthcare (Greer et al., 2014).

One of the best known examples of this influence of the EU in healthcare based on other provisions than article 168, are the rulings of the European court of justice (ECJ) on the Kohll and Decker cases. Within both cases, the ECJ ruled that the free movement of goods and services applies to healthcare, which allowed both Kohll and Decker to respectively get their glasses and orthodontic care reimbursed in another Member State (European Court of Justice, 1998a, 1998b). These rulings eventually led to the establishment of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (European Parliament and Council of the European Union, 2011).

The rulings in the Kohll and Decker cases as well as the establishment of the patient rights directive are examples of how the EU influences areas that are outside of the five policy areas in which it has exclusive competence. There are a few principles that regulate the power of the EU, which need to be taken into account before being allowed to interfere in areas where it has no exclusive competence. The first is the principle of subsidiarity, which states that the EU *"does not take action (except in the areas that fall within its exclusive competence), unless it is more effective than action taken at national, regional or local level"* (EUR-Lex, 2016c). The second principle is that of proportionality,

which states that *"the action of the EU must be limited to what is necessary to achieve the objectives of the Treaties"* (EUR-Lex, 2016b). In addition to the competences the EU has regarding its internal policy, the EU also has external competences according to which the EU *"may conclude, within the framework of its competences, external agreements with non-EU countries or international organisations, which are binding on the EU's institutions and on EU countries"* (EUR-Lex, 2016a).

Recently, the EU's power in both internal and external affairs have been critiqued by multiple Member States for limiting the sovereignty of the individual Member States. Scientific studies on the exact extent to which the powers of the EU have influenced areas such as healthcare remain scarce. Greer (2006, p. 134) argues that the EU has gained competence in the area of health, by *"changing the legal environment under which health systems contract employees, purchase goods, finance services, and organize themselves"*. Similarly, Mossialos and Lear (2012) describe how EU competition law could limit the options of national healthcare systems. However, both Greer (2006) and Mossialos and Lear (2012) limit themselves to stating that the influence of the EU has increased in the field of health over the years, without setting out a detailed description of where exactly the EU has gained competence. Furthermore, both authors give a description of how competition law can affect healthcare as a whole, without going into detail in specific healthcare fields (Greer, 2006; Mossialos & Lear, 2012).

This study tries to fill this gap in scientific literature, by looking into the extent to which the EU is involved in a specific area of healthcare, namely pre- hospital emergency medical services (pre-hospital EMS). Pre-hospital EMS is a suitable area of study, as it is present in every EU member state and the tasks that are fulfilled are similar in each member state. In addition, this study will look at the extent to which the effects of this involvement on national pre-hospital EMS systems has been studied in the scientific literature.

1.1 Goals and research questions

The aim of this study is to gain insights into the extent to which the EU is involved in the area of pre-hospital EMS and to create a comprehensive overview of EU policies affecting this field. In addition, this study aims to get an insight into the reasons behind this involvement, as well make an inventory of the studies discussing the effects this involvement has on national pre-hospital EMS systems.

To reach these goals, the following research question was used:

To what extent is the EU involved in the field of pre-hospital EMS and to what extent have the effects of this involvement on pre-hospital EMS systems been studied in scientific literature?

To answer this question, the following sub-questions were used:

1. What European treaties, directives, recommendations, regulations, decisions and opinions are applicable to pre-hospital EMS and what are their goals?
    a. Why did the EU decide to legislate in this specific area?
    b. Were any of these areas subject to ECJ rulings and what was the scope of these cases?
    c. To what extent have these treaties, directives, recommendations, regulations, decisions and opinions been studied in scientific literature regarding their effects on national pre-hospital EMS systems?

2. What external agreements did the EU conclude that affect or could affect pre-hospital EMS in the EU Member States and what are their goals?
    a. Why did the EU decide to legislate in this specific area?
    b. To what extent have these external agreements been studied in scientific literature regarding their effects on national pre-hospital EMS systems?

2 Theory

In this chapter, a short description of how EMS is organised in the EU Member States is given, to get an insight into what this specific field of healthcare entails. In addition, a more detailed description is given of the three principles regulating EU power in areas that are outside of its exclusive competence, namely subsidiarity, proportionality and conferral. Last, the variety of policy instruments available to the EU are described, which serve as a framework for the analysis of EU involvement in the area of pre-hospital EMS.

2.1 Emergency medical services in the EU

According to the WHO (2008, p. 16), *"Emergency medical service systems form an integral part of any public health care system: their primary function is to deliver emergency medical care in all emergencies, including disasters".* The WHO (2008) divides EMS systems in two broad categories, namely pre-hospital EMS and in-hospital EMS. Pre-hospital EMS can cover a wide range of services that are involved in the provision of care at the site of the adverse medical event and during transport of the patient to an institutional setting (WHO, 2008). In-hospital EMS covers the institutions that can provide 24/7 emergency care in an institutional setting, often the emergency department of a hospital (WHO, 2008). In figure 1, an overview can be found of the elements of an emergency medical system, together with the services involved in each element.

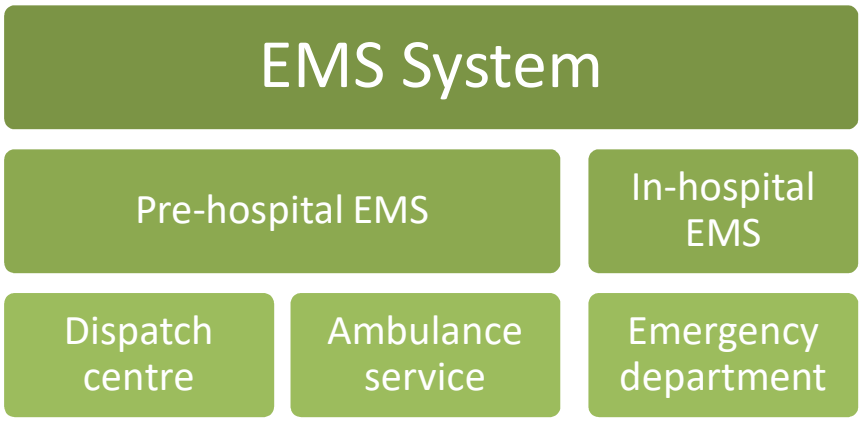

Figure 1. The elements of an Emergency Medical Service System in the EU (WHO, 2008)

As shown in figure 1, pre-hospital EMS consists of two main services, namely the dispatch centre and an ambulance service. In case of an adverse medical event, assistance is requested at the dispatch centre by a person dialling 112 (WHO, 2008). How dispatch centres are organized and who answers the 112 call is up to the Member States and differs within the EU (WHO, 2008). Depending on the urgency of the adverse medical event, the available transportation modes and the condition of the patient, the

dispatch centre selects and requests suitable transportation (WHO, 2008). The transportation mode that is most often used is a road ambulance, which is requested at a (local) ambulance service (WHO, 2008). In most EU countries, other transportation modes such as helicopters, airplanes and boats are available as well (WHO, 2008). Road ambulances are generally divided into three types according to the most recent EU standard 1978:2007 + A2:2014, as shown in table 1 (CEN, 2014).

Table 1. Categorization of road ambulances according to CEN 1978:2007 + A2:2014 (CEN, 2014, p. 10)

Type of road ambulance	**Definition**
Type A – Patient transport ambulance	"Road ambulance designed and equipped for the transport of patients who are not expected to become emergency patients"
Type B – Emergency ambulance	"Road ambulance designed and equipped for the transport, basic treatment and monitoring of patients"
Type C – Mobile intensive care unit	"Road ambulance designed and equipped for the transport, advanced treatment and monitoring of patients"

The WHO (2008) report also showed that the three types of road ambulances are used in different degrees in the EU Member States. In figure 2, an overview can be found of the types of road ambulances used in the different EU Member States.

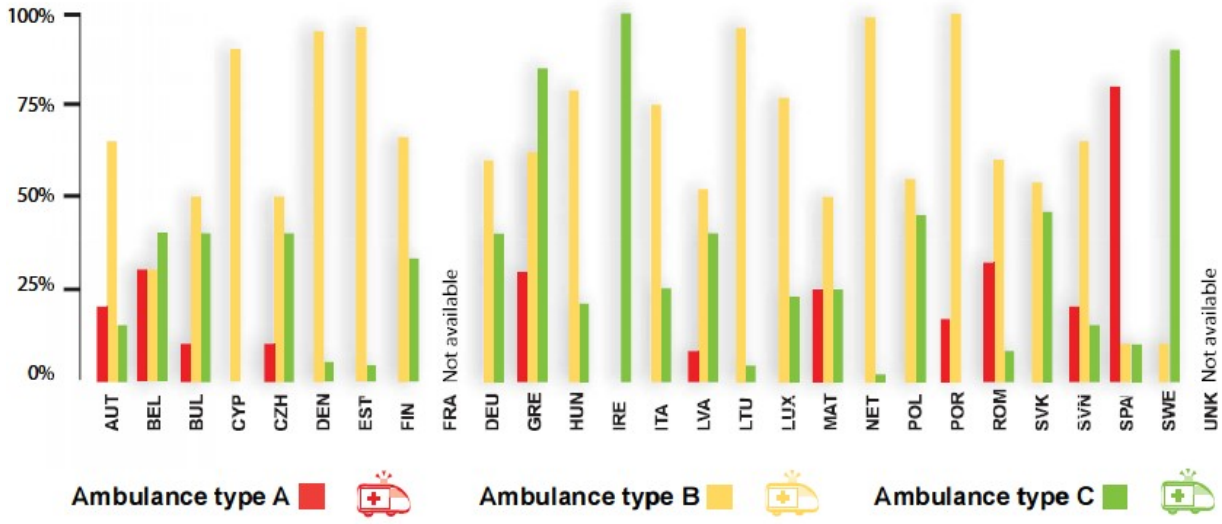

Figure 2. Percentage of ambulance types by EU Member State (WHO, 2008, p. 36)

In-hospital EMS is generally delivered at the emergency department of a hospital, where initial treatment is given to the patient (WHO, 2008). In most cases, the emergency department uses a triage system to determine which patients should be prioritized and thereby should be treated first (WHO, 2008). As shown in figure 3, almost all emergency departments in the EU use a triage system.

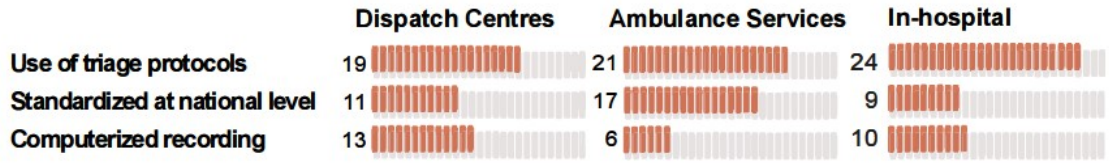

Figure 3. The use of triage protocols in the EU (WHO, 2008, p. 41)

In addition, some Member States introduced triage systems in their dispatch centres and ambulance services. The WHO (2008) report also investigated whether or not these triage systems were standardized at the national level and how many Member states made use of computerized recording (WHO, 2008). This study focuses on pre-hospital EMS systems.

2.2 The principles of subsidiarity, proportionality and conferral

The principles of subsidiarity has been established in the Treaty of Maastricht, which was signed in 1992 and came into force in 1993 (European Union, 1992). Even though the Single European Act of 1987 already implicitly incorporated the subsidiarity principle into its environmental policy, the Treaty of Maastricht remains to be seen as the official establishment of the subsidiarity principle in the EU (European Parliament, 2016). Currently, the subsidiarity principle can be found in article 5(3)of the treaty on European Union (TEU), which states:

"Under the principle of subsidiarity, in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level" (European Union, 2012a)

According to Reid (2010), there are three situations where the principle of subsidiarity implies that EU action should be preferred over Member State action. First, situations where the issue at hand has transnational aspects, which can only be satisfactorily regulated at EU level (Reid, 2010). Second, situations where lack of EU regulation would

be in stride with the EU treaties (Reid, 2010). Last, situations where EU action would be more efficient than Member State action and thereby would produce a clear benefit (Reid, 2010).
In addition to the principle of subsidiarity, the TEU contains a second principle which governs the use of EU competences, namely the principle of proportionality. The proportionality principle can be found in article 5(4) of the TEU, which states:

"Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties" (European Union, 2012a)

The proportionality principle implies that the form and content of action taken by the EU should not be disproportional in relation to its objective (EUR-Lex, 2016b; Reid, 2010).
A third principle governs the limits of EU competence, which is called the principle of conferral. This principle can be found in article 5(2) and governs the limits of EU competences (European Union, 2012a). This articles states that:

"Under the principle of conferral, the Union shall act only within the limits of the competences conferred upon it by the Member States in the Treaties to attain the objectives set out therein. Competences not conferred upon the Union in the Treaties remain with the Member States" (European Union, 2012a)

The principle of conferral thereby implies that EU action should limit itself to those areas in which it has competence according to the treaties (European Union, 2012a).

2.3 EU policy instruments

According to Versluis, Keulen, and Stephenson (2011), there are many reasons why it is important to categorize policy instruments when analyzing them. Categorization not only provides insight into the characteristics of the specific policies, but also why a specific policy instrument was chosen (Versluis et al., 2011). Versluis et al. (2011) uses the categorization scheme as developed by Hood and Margetts (2007), which distinguishes between nodality, authority, treasure and organization instruments. Nodality instruments refer to the use of information to confront people with current issues and problems (Hood & Margetts, 2007; Versluis et al., 2011). According to the European Commission (2015), the following nodality instruments are used at EU level, namely *"information and publicity campaigns, training, guidelines, disclosure requirements, and/or the introduction of standardised testing or rating systems".* Authority instruments on the other hand make use of legal powers, which include *"treaties, regulations, directives, decisions,*

recommendations, opinions, case law and general principles of law" (Hood & Margetts, 2007; Versluis et al., 2011). Treasure instruments make use of money to reach certain goals, and include *"taxes, charges, fees, fines, penalties, liability and compensation schemes, subsidies and incentives, deposit-refund systems, labelling schemes and tradable permit schemes"* (European Commission, 2015; Hood & Margetts, 2007; Versluis et al., 2011). The last policy instruments, the organization instrument, makes use of formal organizations to confront public problems, including *"the provision of goods and services, market creation, governmental reorganization and use of family, friends and voluntary organizations"* (Craft, 2011, p. 3; Hood & Margetts, 2007; Versluis et al., 2011).

Versluis et al. (2011) argue that the EU mainly makes use of authority instruments, which can be further subdivided into multiple types of regulatory instruments. Reid (2010) and Versluis et al. (2011) both describe the instruments available to the EU including both legally binding and non-legally binding instruments. The Treaties created by the European Union are seen as the primary source of EU law and all other legal acts should be based on these treaties. Legal acts of the European Union can be further subdivided into legally binding acts, namely regulations, directives and decisions; and non-legally binding acts, namely recommendations and opinions (Reid, 2010). In addition to these legal acts, rulings of the court of justice of the European Union (CJEU) are seen as a policy instruments, where the CJEU settles legal disputes and ensures that EU law is interpreted and applied in the same way throughout the EU (European Union, 2016; Reid, 2010). The last authority instrument described by Reid (2010), are the general principles of law, which are used by the CJEU and are derived from legal traditions within the EU Member States (Reid, 2010). Examples given by Reid (2010) include legal certainty, proportionality and non-discrimination. In addition to the authority instruments the EU can use for internal affairs, the EU is also allowed to conclude external agreements with international organizations and non-EU countries, there where it has competence to do so (EUR-Lex, 2016a). These external agreements are then binding on the Member States of the EU and its institutions (EUR-Lex, 2016a).

3 Methods

As the extent to which the EU is involved in the area of pre-hospital EMS is a complex area of study and has not yet been comprehensively reviewed before, a scoping review is used (Arksey & O'Malley, 2005). According to Polit and Beck (2012, p. 656), a scoping review can be described as *"a preliminary investigation that clarifies the range and nature of the evidence base".* This definition is in line with the definition given by Arksey and O'Malley (2005, p. 21), who describe that a scoping review aims *"to map rapidly the key concepts underpinning a research area and the main sources and types of evidence available".*

3.1 Search strategy

According to Arksey and O'Malley (2005) one should be as comprehensive as possible when scoping the field for relevant literature. Within this scoping review, multiple data sources were used, including electronic databases, the Maastricht university library and websites of relevant institutions.

To search for EU policies in the field of pre-hospital EMS, the EUR-Lex database was used, together with the websites of the European Commission and the European Parliament. Search terms that were used included: "emergency medical service", "dispatch centre", "ambulance care", and "ambulance service". In addition, a search for case-law of the Court of Justice (ECJ) was conducted using the Curia database. Looking at these court cases provided an insight into the views of multiple parties towards the power of the EU in the field of pre-hospital EMS, including but not limited to EMS organizations within the member states, the European Commission and the ECJ itself. Search terms that were used included: "ambulance", "dispatch centre", and "emergency medical service". Each search that was conducted was limited to the following subject matter: "Transport", "Social security", "Public health", "Principles, objectives and tasks of the Treaties", "Internal market - Principles", "Freedom to provide services", "Freedom of movement for workers", "Free movement of goods", "Employment", "Data protection", "Consumer protection", "Competition", and "Freedom of establishment". Subject matter was selected based on the findings of the first search, as well as pre-existing knowledge of the research on the fields applicable to pre-hospital EMS. In total, 121 cases were identified, which, after removing duplicates, resulted in 115 cases that could possibly be related to pre-hospital EMS. After applying the pre-defined inclusion and exclusion criteria, namely language (English, German and Dutch), title relevance and content relevance, 7 cases were identified that applied to pre-hospital EMS, as shown in figure 4.

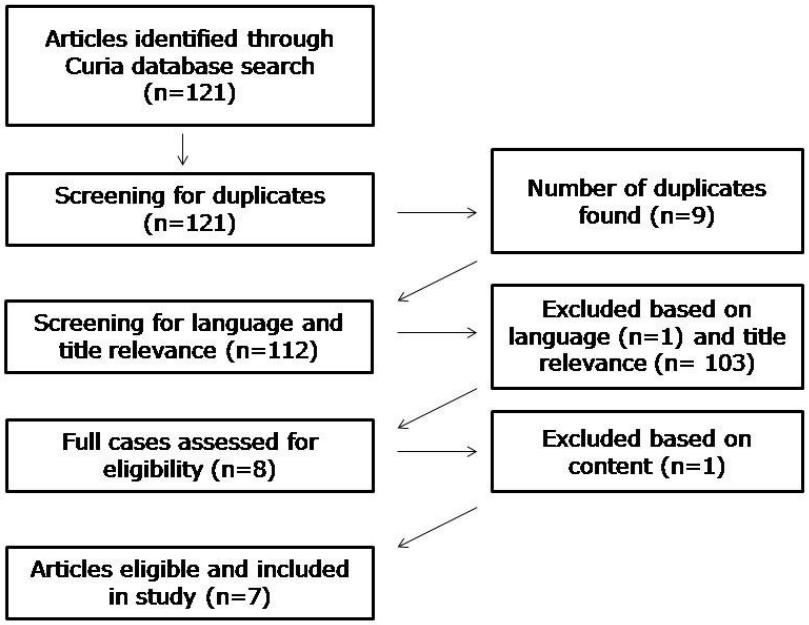

Figure 4. Selection of eligible case-law

To investigate the effects of external agreements between the EU and non-EU countries, a recent agreement was selected, namely the CETA between the EU and Canada. This agreement will serve as an example and unit of analysis for this study.

Based on these findings of the search for policies and case-law, a second search was conducted to investigate the extent to which the effects of these policies on national emergency medical systems have been studied in scientific literature. To search for scientific articles and books, the following electronic databases were searched: PubMed, Medline, BMJ, Cochrane Library, Sciencedirect, and the WHO Library. As this search was dependent on the search that was conducted first, a list with search terms was created during the study, which can be found in table 4 in appendix 1.

Articles found through this search strategy, were compared to the inclusion and exclusion criteria that were established before the start of the search. Inclusion and exclusion criteria include language (any language other than English was excluded) and title and abstract relevance (only articles in which the topic under study is mentioned in the title or abstract were included). From relevant articles found, the bibliographies were checked to see whether any relevant sources are cited, which did not come up during the literature search (Arksey & O'Malley, 2005). These sources were included as well, when they met the predefined inclusion and exclusion criteria.

3.2 Data analysis

Authority instruments identified through the first search were inventoried and categorized based on the categorization scheme described in section 2.3. Authority instruments were then divided into broad areas of influence that were used as headings for section 4.1.1 till 4.1.7. All authority instruments were read and summarized, to allow for the researcher to see where these instruments could affects pre-hospital EMS systems. A similar procedure was used to analyse the ECJ cases identified. First they were categorized based on their field of application and then read and summarized per case. The headings of CETA were scanned to see which were likely to apply to pre-hospital EMS and which were not. The chapters that applied to pre-hospital EMS were read fully and summarized.

The second search, the search for scientific literature, was analysed differently, as here not just the articles themselves were of importance, but also the availability of articles was of interest. For each search, relevant articles were read to see whether or not pre-hospital EMS systems were mentioned throughout the article. Whenever no relevant articles could be identified, this was reported as a finding. In these cases the search terms referring to pre-hospital EMS were left out and the search was repeated to see whether this resulted in any relevant articles.

4 Results

This chapter provides an overview of the authority instruments used by the EU and how these instruments influence national pre-hospital EMS systems within the EU. The first part of this chapter will focus on the identification of different authority instruments used by the EU that influence pre-hospital EMS systems within the EU. The second part of this chapter provides an example of an external agreement concluded between the EU and a non-EU country. Here a description will be given of the possible effects this external agreement might have on pre-hospital EMS systems within the EU. The third part of this chapter focuses on the scientific literature and to what extent this literature has covered the effect the identified authority instruments and external agreements have on pre-hospital EMS systems within the EU.

4.1 Authority instruments

Authority instruments used by the EU that either directly or indirectly affect pre-hospital EMS are various. An overview of the authority instruments identified in this study can be found in table 5 in appendix 2 and each identified instrument is explained in more detail in section 4.1.1 till 4.1.7.

4.1.1 Single European Emergency call number

In 1991, a decision of the Council of the European Communities introduced a single European emergency call number throughout the EU, namely 112 (Council of the European Communities, 1991). This decision required member states to introduce 112 as emergency call number, which was either taken as the single emergency call number or introduced parallel to already existing emergency call numbers (Council of the European Communities, 1991). Currently, the 112 emergency number can be called throughout the whole EU to reach pre-hospital EMS, fire brigades and the police (EENA, 2016).

4.1.2 Working times

Directive 2003/88/EC, also referred to as the EU's working time directive, lays down *"minimum safety and health requirements for the organisation of working time"* (European Parliament and Council of the European Union, 2003, p. 9). This directive not only lays down minimum periods of rest a worker should have per day and/or week, but also specifies requirements regarding annual leave, breaks and maximum working time per week. In addition, this directive specifies measures that should be taken by member states regarding night work, shift work and work patterns (European Parliament and Council of the European Union, 2003). This directive applies to all sectors, which implies that personnel working in a dispatch centre or ambulance service is covered by the directive as well. According to the directive, member states should take all necessary

measures to ensure that the provisions of this directive are applied to all workers (European Parliament and Council of the European Union, 2003).

4.1.3 Technical requirements for pre-hospital EMS

The European Committee for standardization (CEN) was founded in 1961 and is recognised by both the EU and the European Free Trade Association (EFTA) as the responsible agency for the development and publication of voluntary European standards and technical specifications (CEN, 2016a, 2016b). The aims of these voluntary standards include *"improving safety, quality and reliability of products, services, processes; reinforcing the Single Market and supporting the economic growth and the spread of new technologies and innovation"* (CEN, 2016a). In the field of pre-hospital EMS, multiple CEN standards have been published that have been taken up by most EU member states. Standards that were identified mainly focused on medical vehicles and their equipment. No standards were found regarding dispatch centres. An overview of the standards affecting pre-hospital EMS can be found in table 2.

Table 2. EU standards related to pre-hospital EMS (European Commission, 2016b)

Standard (most recent version)	**Title**
EN 1789:2007+A2:2014	Medical vehicles and their equipment - Road ambulances
EN 13718-1:2014	Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances
EN 13718-2:2015	Medical vehicles and their equipment - Air ambulances - Part 2: Operational and technical requirements for air ambulances
EN 1865-1:2010+A1:2015	Patient handling equipment used in road ambulances - Part 1: General stretcher systems and patient handling equipment
EN 1865-2:2010+A1:2015	Patient handling equipment used in road ambulances - Part 2: Power assisted stretcher
EN 1865-3:2012	Patient handling equipment used in road ambulances - Part 3: Heavy duty stretcher
EN 1865-4:2012	Patient handling equipment used in road ambulances - Part 4: Foldable patient transfer chair
EN 1865-5:2012	Patient handling equipment used in road ambulances - Part 5: Stretcher support
EN 794-3:1998+A2:2009	Lung ventilators - Part 3: Particular requirements for emergency and transport ventilators

4.1.4 Free movement of professionals

The right to free movement of workers is laid down in article 45 of the treaty on the functioning of the European Union (TFEU), which states that *"freedom of movement for*

workers shall be secured within the Union" (European Union, 2012b). This article allows workers to move freely throughout the EU, with the exception of those working in public services (European Union, 2012b). This raises the question whether or not pre-hospital EMS is a public service.

A public service is generally defined as a service provided to the public with the aim to help others instead of making profit (Cambridge University, 2016; Merriam-Webster, 2016). The WHO (2008) investigated pre-hospital EMS services and concluded that both ambulance services and dispatch centres can be public enterprises, private enterprises or a combination of both, as shown in figure 5.

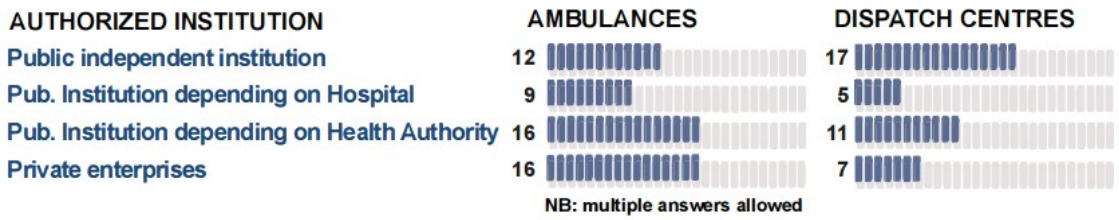

Figure 5. Institutions delivering pre-hospital EMS (WHO, 2008)

According to Bos, Krol, Veenvliet, and Plass (2015), most countries within the EU have both public and private enterprises providing ambulance services. They identified only four countries, Croatia, the Czech Republic, Latvia and the UK, where ambulance services were completely public (Bos et al., 2015). This suggests that it depends on the country and sometimes even the region whether or not pre-hospital EMS services are considered public services.

In addition to the free movement of pre-hospital EMS professionals, which is allowed under article 45 TFEU, the EU has introduced a directive that makes it possible for pre-hospital EMS professionals to practice their profession in another EU country. Directive 2005/36/EC on the recognition of professional qualifications established rules regarding the acceptance of qualifications obtained in an EU Member State when pursuing a regulated profession in another Member State (European Parliament and Council of the European Union, 2005). Directive 2005/36/EC has been amended in 2013 by Directive 2013/55/EU which changed and added to the first Directive (European Parliament and Council of the European Union, 2013). A non-exhaustive list of regulated professions that fall under Directive 2005/36/EC can be found in the regulated professions database.

Professionals working in the pre-hospital EMS field can look up the profession they are currently plasticising in their Member State and whether or not their qualifications will be accepted in the Member State in which they would like to pursue a career (European Commission, 2016c). The database also provides an overview of decisions taking by the host countries regarding the request to get ones qualifications recognised in prior cases.

4.1.5 Cross-border collaboration

In 1980, the EU member states signed the European outline convention on trans-frontier cooperation between territorial communities or authorities (Council of Europe, 1980). The aim of this convention was to encourage the conclusion of cross-border agreements between local and regional authorities in the EU member states (Council of Europe, 1980). In addition, this convention set out to take away obstacles that would hinder local and regional authorities when concluding cross-border agreements (Council of Europe, 1980). Article 3.2 of the outline convention states the following: *"If the contracting parties deem it necessary to conclude inter-state agreements, these may inter alia establish the context, forms and limits within which territorial communities and authorities concerned with transfrontier co-operation may act. Each agreement may also stipulate the authorities or bodies to which it applies" (Council of Europe, 1980)*. This article indicates that it is up to the member states to conclude inter-state agreements whenever they deem it necessary to specify the limits of cross-border agreements concluded between the member states involved. Whether or not ambulance services and/or dispatch centres are allowed to conclude cross-border agreements will largely depend on the framework that is set within concluded inter-state agreements.

4.1.6 Financing of pre-hospital EMS – a cross-border perspective

There are currently two arrangements within the EU that allow for the reimbursement of care received in another member state than where the patient is insured, the so-called state of affiliation. Regulation 883/2004 applies to the reimbursement of both planned and emergency care, whereas Directive 2011/24 only applies to planned care. Taking into account the nature of pre-hospital EMS, which in principle is always emergency care, only Regulation 883/2004 applies to this situation.

Article 19 or Regulation 883/2004 states that *"an insured person and the members of his family staying in a Member State other than the competent Member State shall be entitled to the benefits in kind which become necessary on medical grounds during their stay, taking into account the nature of the benefits and the expected length of the stay"* (Council of the European Communities, 2004, p. 30). This would imply that any EU national residing in a member state other than the member state in which he or she is insured, either temporarily or permanently, is entitled to pre-hospital EMS as long as it is necessary on medical grounds. Reimbursement of these benefits is also arranged in article 19, which states *"these benefits shall be provided on behalf of the competent institution by the institution of the place of stay, in accordance with the provisions of the legislation it applies, as though the persons concerned were insured under the said legislation"* (Council of the European Communities, 2004). This implies that pre-hospital

EMS provided are reimbursed by the insurance of the patient with the same amount that would have been reimbursed if the patient were insured in the country where care is provided.
This regulation, hereby, ensures two main things. First, a citizen travelling throughout the EU has the guarantee that pre-hospital EMS will be provided, no matter where her or she is insured. Second, the pre-hospital EMS has the guarantee that the insurance company of the patient will fully reimburse the costs made, as would be the case for patients insured in that particular country.

4.1.7 Public procurement

Directive 2014/24/EU also referred to as the public procurement directive lays down rules regarding tenders for public contracts (European Parliament and Council of the European Union, 2014). Amongst others, this directive establishes that tender procedures should be transparent in their dealings and should treat all applicants equal and are not allowed to discriminate between them (European Parliament and Council of the European Union, 2014). According to article 67, *"contracting authorities shall base the award of public contracts on the most economically advantageous tender"* (European Parliament and Council of the European Union, 2014, p. 134).
Pre-hospital EMS is a service for which the responsibility most often lies with public authorities, that either perform the service themselves or purchase services from others (WHO, 2008). Whenever these public authorities choose to purchase services, they make use of tenders and need to take the rules laid down in Directive 2014/24/EU into account.

4.2 EU Case law

A total of seven cases were found, where the ECJ ruled on a subject that concerned or was related to pre-hospital EMS. All seven cases were related to the provision of pre-hospital EMS services and overall concerned the awarding of public service contracts and related issues. Within this section each of these cases is shortly described.

4.2.1 Case C-76/97

The first case that was put before the ECJ was Case C-76/97 between Walter Tögel and Niederösterreichische Gebietskrankenkasse. Within this case, an important distinction is made between the transport element of ambulance care and the healthcare element of ambulance care (ECJ, 1998). According to the ECJ, services that include both the transport and the healthcare element should be treated according to the rules laid down in Directive 92/50 EEC, that apply to the element that has the overhand (ECJ, 1998).

4.2.2 Case C-475/99

The second case that was put before the ECJ was Case C-475/99 between Ambulanz Glöckner and Landkreis Südwestpfalz. In this case, Landkreis Südwestpfalz refused the renewal of authorization for Ambulanz Glöckner on the basis that public ambulance services were operating at only 26 percent of their capacity. Ambulanz Glöckner brought an action before the administrative Court (Verwaltungsgericht), who ruled that "*since Ambulanz Glöckner had operated ambulance services for more than seven years, it was clear, according to the national court, that its activity was not prejudicial to the operation or existence of the public ambulance service*" (ECJ, 2001, p. 8144). Landkreis Südwestpfalz appealed against this judgement at the Oberverwaltungsgericht Rheinland-Pfalz, who referred the following question to the ECJ: *"Is the creation of a monopoly for the provision of ambulance services over a defined geographical area compatible with Article 86(1) EC and Article 81 and 82 EC?"* (ECJ, 2001, p. 8145).

The ECJ ruled that for the decision of the Landkreis Südwestpfalz was not breaching the provisions laid down in the TFEU. They argued that whenever public pre-hospital EMS are unable to meet the demand within the specific geographical region, authorization should have been provided (ECJ, 2001). However, as public pre-hospital EMS were operating at only 26 percent of their capacity, this does not apply to the Ambulanz Glöckner Case.

4.2.3 Case C-532/03

In Case C532/03, the Commission of the European Communities asked the ECJ to declare that Ireland failed to fulfil its obligations under community law, by permitting Dublin City Council to provide pre-hospital EMS without having undertaken prior advertising and thereby not meeting the rules regarding public service contracts, at that point in time laid down in Directive 92/50/EEC (ECJ, 2007). The ECJ dismissed this request, as the Commission was not able to prove that Ireland failed to fulfil its obligations (ECJ, 2007). According to the ECJ (2007), *"neither the Commission's arguments nor the documents produced demonstrate that there has been an award of a public contract, since it is conceivable that DCC provides emergency ambulance services in the exercise of its own powers derived directly from statute. Moreover, the mere fact that, as between two public bodies, funding arrangements exist in respect of such services does not imply that the provision of the services concerned constitutes an award of a public contract which would need to be assessed in the light of the fundamental rules of the Treaty"*.

4.2.4 Case C-160/08

Similar to Case C532/03, the Commission of the European Communities asked the ECJ to declare that Germany failed to fulfil its obligations under community law in Case C-160/08 (ECJ, 2010). According to the Commission, Germany failed its obligations under

Directive 92/50/EEC and Directive 2004/18EC, by not making a pubic call for tenders, not awarding the respective contracts transparently and not publishing notices of contracts awarded (ECJ, 2010). The ECJ declared that *"by failing to publish notices of the results of the procedure for the award of contracts, the Federal Republic of Germany has failed to fulfil its obligations"* (ECJ, 2010). The remaining requests regarding the public call for tenders and transparent awarding of contracts of the Commission were dismissed by the ECJ (ECJ, 2010).

4.2.5 Case C-274/09

Case C-274/09 concerns a dispute between a private provider of pre-hospital EMS (Stadler) and the authority responsible for pre-hospital EMS within the Passau region. Stadler provided pre-hospital EMS services until the end of 2008, when their contract was terminated (ECJ, 2011). The termination of this contract was contested in multiple courts with the Oberlandesgericht in Munich eventually asking for an interpretation of article 1(2)(a) and (d) and Article 1(4) of Directive 2004/18/EC from the ECJ (ECJ, 2011). The ECJ (2011) interpreted these articles in light of the current case and stated that the contract in this specific case should be classified as a service concession. Directive 2004/18/EC defines a services concession as follows *"a contract of the same type as a public service contract except for the fact that the consideration for the provision of services consists either solely in the right to exploit the service or in this right together with payment"* (European Parliament & Council of the European Union, 2004).

4.2.6 Case C-113/13

In Case C-113/13, the ECJ was asked for an interpretation of articles 49, 56, 105 and 106 TFEU in relation to the organization of urgent and emergency ambulance services at regional and local level in Italy (ECJ, 2014). The ECJ ruled that article 49 and 56 TFEU should be interpreted as not being in stride with the national regulations, which in this case means that *"entrusting the provision of urgent and emergency ambulance services on a preferential basis and awarding them directly to voluntary associations covered by the agreement"* is allowed (ECJ, 2014).

4.2.7 Case C-50/14

The most recent case, Case C-50/14 was also put before the ECJ by an Italian court, which asked for further clarification of article 49 and 56 TFEU (ECJ, 2016). Similar to Case C-113/13, the ECJ (2016) ruled that local authorities are allowed *"to entrust the provision of medical transport services by direct award, without any form of advertising, to voluntary associations, provided that the legal and contractual framework in which the activity of those associations is carried out actually contributes to the social purpose and*

the pursuit of the objectives of the good of the community and budgetary efficiency". This implies that authorities are allowed to privilege voluntary non-profit organizations by directly awarding service contracts to them without advertising.

4.3 External agreements

As outlined in section 2.3, the EU can conclude external agreements with international organizations and non-EU countries, there where it has competence to do so (EUR-Lex, 2016a). These external agreements can be used in addition to the authority instruments the EU uses for internal affairs, which are outlined in section 4.1. The external agreements concluded by the EU are various with most of them focusing on trade (EUR-Lex, 2017). To illustrate the effect of these external agreement on national pre-hospital EMS systems, a recent trade agreement has been selected, which is described in more detail in this chapter.

4.3.1 Comprehensive Economic and Trade Agreement (CETA)

One of the most recent external agreements concluded between the EU and a non-EU country is the comprehensive economic and trade agreement (CETA). CETA is an agreement between the EU and Canada and was signed in October 2016 (European Commission, 2016a). The European Parliament has passed the CETA on the 15th of February, which only leaves ratification by the national parliaments (Europa Nu, 2017). The main aim of the CETA is to boost the trade between Canada and the EU and thereby creating new jobs and growth both in the EU and Canada (European Commission, 2016a).

In the area of pre-hospital EMS, chapter 9 of CETA is of particular interest, as it refers to cross-border trade in services. Pre-hospital EMS is a service, which depending on how these services are organized and which organizations provide them, will fall under the provision of this chapter (European Union & Canada, 2016). Article 9.2.a states that chapter 9 does not apply to *"services supplied in the exercise of governmental authority".* This implies that governmental authorities responsible for the provision of pre-hospital EMS that decide to provide these services themselves do not fall under this provision. However, as stated in section 4.1.4, most member states have both public and private enterprises providing pre-hospital EMS. This implies that at least part of the member states will fall under the provisions of this chapter and thereby can be affected by CETA.

A total of fifteen EU member states included reservations to this provision in the form of a negative list in annex 1 of CETA (European Union & Canada, 2016). This negative list implies that activities included in this list are not opened up for free trade. EU member states that included reservations regarding pre-hospital EMS can be found in table 6 in appendix 3. The majority of countries that included a reservation in the annex of the

CETA did so by including the following right, namely the *"right to adopt or maintain any measure with respect to the supply of privately funded hospital, ambulance, and residential health services other than hospital services"* (European Union & Canada, 2016). Other reservations focused on the on the demand side, stating that local availability of services and managers should be considered, as well as allowing a needs based limit on establishment (European Union & Canada, 2016).

The remaining 13 EU member states that did not include any reservations in the annex of the CETA fall fully under the provisions set out in chapter 9 of CETA. In these member states, no reservations are in place that could prevent Canadian ambulance services from establishing themselves in its territory. These services would then be allowed to enter into the competition for a public tender and should be treated as any other service applying for the tender under Directive 2014/24/EU.

4.4 Scientific literature

Within this section an overview is given of the extent to which the effects of the involvement at EU level on national pre-hospital EMS systems has been studied in scientific literature. For each area of involvement, a short description of the main findings is given in section 4.3.1 till 4.3.7.

4.4.1 Single European Emergency call number

Scientific literature on the effects of a single European emergency call number on national pre-hospital EMS systems is limited. No scientific articles were found, but the WHO (2008) published a report on pre-hospital EMS within the EU, where the single emergency call number and its effects at the national level are discussed. According this study by the WHO (2008), all EU countries have introduced the 112 emergency call number. In only 10 member states, 112 is the only number to reach pre-hospital EMS. In 2 other member states, 112 is the only number to reach pre-hospital EMS in some of its regions. Other regions remain using a parallel number to reach pre-hospital EMS (WHO, 2008). In addition, this study showed that 21 countries have an integrated dispatch centre to answer a 112-call by its citizens as shown in figure 5.

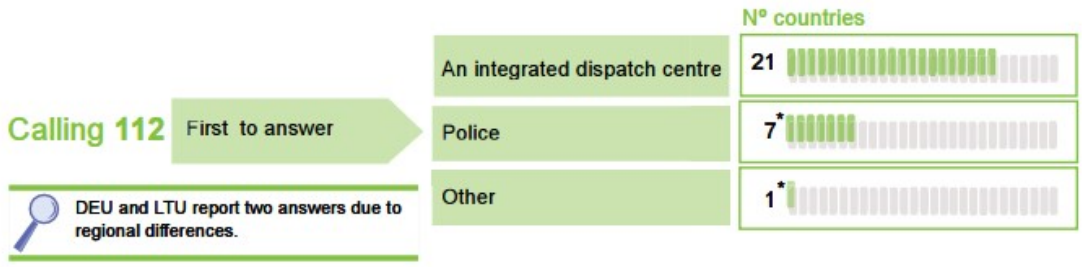

Figure 6. Responsible authorities answering 112 emergency calls within the EU (WHO, 2008)

Figure 5 also shows that in 7 countries the police is responsible for answering 112-calls. According to the WHO (2008) report, Germany is the odd one out, where it depends on the federal state, whether the fire brigade or the red cross is responsible for answering 112-calls from its citizens.

4.4.2 Working times

Articles looking specifically at the effects of the working time directive on personnel working in pre-hospital EMS were not found. Some articles were found that focused more broadly on the effects of this directive on medical professionals in general and other services that are supposed to be operational 24/7. Cairns, Hendry, Leather, and Moxham (2008, p. 421) state that *"Although many industries are affected by the change in the law, medicine poses particular problems because of the need to train junior medical staff and to provide a 24 hour service that can respond to variable demand while ensuring continuity of, often complicated, patient care"*. Another study suggests that problems are likely to occur with the training of sufficient high quality staff and disruption of work rhythms, as well as a reduction in free time (Benes, 2006). Even though these studies focus on other medical professions, it is likely that similar problems could occur in pre-hospital EMS, as these are also services that are supposed to be operational 24/7.

4.4.3 Technical requirements for pre-hospital EMS

Scientific literature on the CEN standards identified in section 4.1.3 was not found. According to CEN (2017b), all members of CEN are obliged to adopt these standards without any modifications. All EU countries are a member of CEN, together with the other countries that are a part of the single market (CEN, 2017a). It can therefore be assumed that all EU countries have at least adopted these standards into their national standardization programme (CEN, 2017a). This, however, does not imply that all organizations in these countries use these standards, as a legal obligation to apply these standards is lacking.

4.4.4 Free movement of professionals

The free movement of professionals, and more particularly healthcare professionals, is a topic that is better researched than the topics described in the previous three sections. A general trend that is observed is the movement of professionals from 'new' member states to 'old' member states, with the shortages thereby created in the 'new' member states not being replenished (Glinos, 2012). The regulated professions database shows that between 2010 and 2015, 511 citizens tried to get their qualification recognised to work as an ambulance nurse in another country (European Commission, 2016c). 85

percent of these appeals were recognised, with only very few cases requiring additional actions such as an aptitude test or adjustment period (European Commission, 2016c). In figure 7 an overview can be found of the countries in which most ambulance nurses applying for the recognition of their qualification obtained their degree. In figure 8, an overview can be found of the countries in which most ambulance nurses applying for the recognition of their qualification would like to carry out their profession.

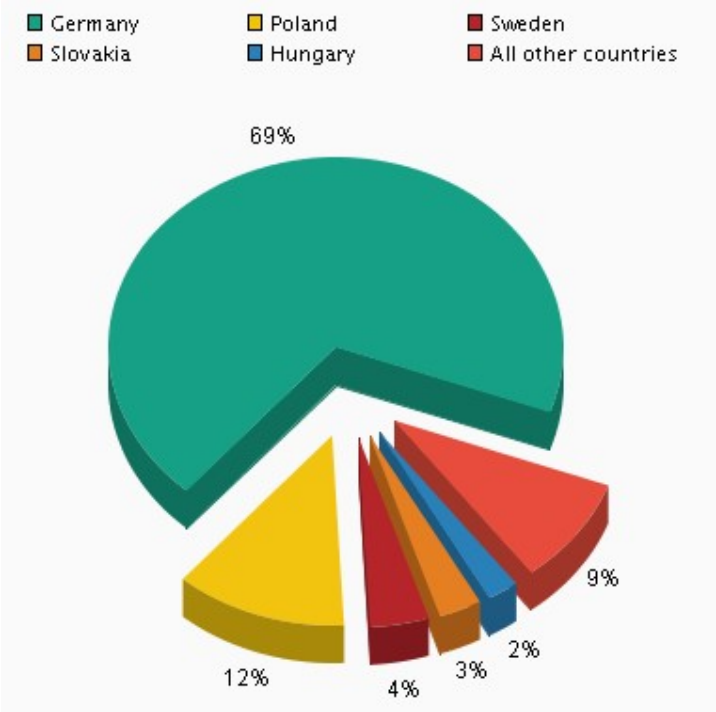

Figure 7. Country in which applicant obtained their qualification (European Commission, 2016c)

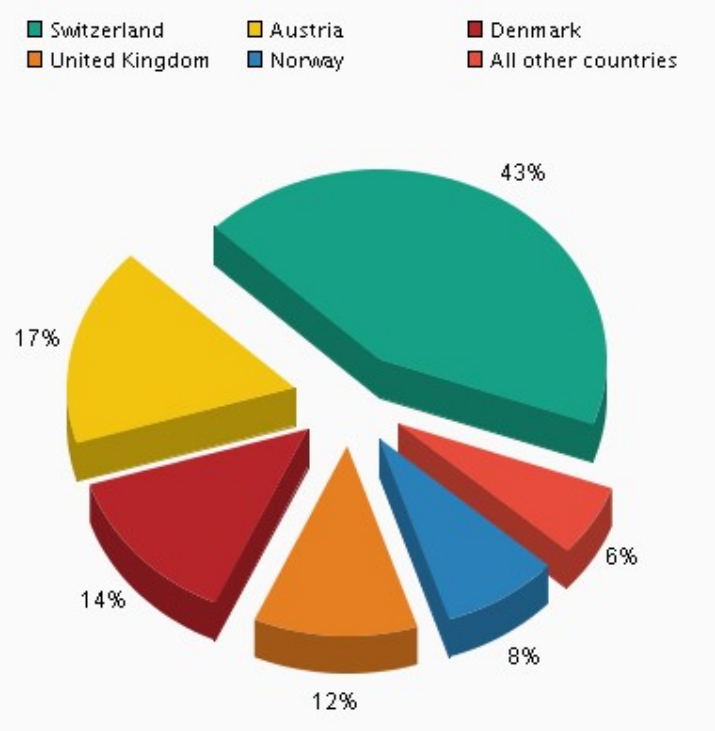

Figure 8. Country in which applicant would like to carry out their profession(European Commission, 2016c)

Other professions related to pre-hospital EMS were not found in the database and therefore no overview of professional mobility could be given.

4.4.5 Cross-border collaboration

Cross-border collaboration between pre-hospital EMS services has been researched in the scientific literature. The Euregion Meuse-Rhine (EMR) is a cross-border region with a long history of cross-border collaboration. Within this region, multiple studies have been published on the topic of cross-border pre-hospital EMS including studies by Jabakhanji et al. (2015) and Ramakers (2014).

Cross-border collaboration described in these articles has been made possible by member states making use of the possibility to conclude agreements under the European outline convention on trans-frontier cooperation between territorial communities or authorities. The Benelux agreement (Benelux, 1986) between the Netherlands, Belgium and Luxembourg is an example of such an agreement. This agreement sets out which authorities and bodies can conclude agreements and which procedures should be adhered to when concluding new agreements. Based on the outline convention and the inter-state agreements concluded, local and regional bodies and authorities are able to conclude agreements on cross-border collaboration. In the field of pre-hospital EMS, most of these

agreements focus on mutual assistance during large-scale incidents and crises or daily assistance, like the collaboration taking place in the EMR

4.4.6 Financing of pre-hospital EMS – a cross-border perspective

The financing of cross-border healthcare is relatively well researched compared to other areas of influence described in this paper. Regulation 883/2004 has been mentioned extensively within the scientific literature. The focus of this research has mainly been on planned cross-border healthcare instead of the financing of healthcare that becomes necessary when abroad. Hatzopoulos and Hervey (2013) for example discuss the course ECJ rulings have taken in the field of planned cross-border healthcare. Glinos, Baeten, Helble, and Maarse (2010) also looked at cross-border healthcare, identifying multiple types of cross-border care. Separate studies focusing on the right to reimbursement of emergency medical care abroad as laid down in article 19 were not identified.

4.4.7 Public procurement

Studies on public procurement in general can be identified. The number of studies focussing on public procurement practices in healthcare are limited. Studies identified are in general published before the implementation of Directive 2011/24/EU and focus on public procurement procedures in single countries. Studies on looking at the effects the new public procurement rules have on national pre-hospital EMS systems were not found. Scientific literature looking at the identified case law regarding public procurement such as Case C-475/99 is also limited. A few books were identified that used the respective cases as examples in their line of argumentation. An example of this is Wendt (2012), who used the example to discuss the developments in competition law. Literature focusing on the specific effects of this case on national pre-hospital EMS systems was not found.

4.4.8 Comprehensive Economic and Trade Agreement

Scientific literature on the recently signed CETA agreement is limited, with articles focussing on the effects of this agreement on national healthcare systems, mainly focusing on the pharmaceutical industry. Lexchin and Gagnon (2013) for example looked at the effects of the CETA on intellectual property within the pharmaceutical market. A second article was published by Lexchin and Gagnon (2014) in 2014, looking at the effects of CETA on the costs of prescription drugs within the EU. No studies were identified that looked at the possible effects of CETA on national pre-hospital EMS systems.

Themes that are a focal point of research on trade agreements in general is the distinction between the use of positive and negative listing (Snape & Bosworth, 1996). The difference between the two is that a positive list includes sectors that are included

within the trade agreement, whereas a negative list approach is used to list sectors that are exempted from the agreements made (Snape & Bosworth, 1996). Each approach has its own advantages and disadvantages, which are studied in the literature extensively. The main advantage of positive listing is that at a later stage, no services will come to fall under the agreement that were not intended to. This in turn is its own disadvantage, as no additional services can be added at a later stage (O'Connor, 2012). O'Connor (2012) argues that the positive listing approach discriminates against new and innovative services, that cannot benefit from free trade established under past trade agreements. Negative listing has the opposite effect, where new and innovative services cannot be exempted from the rules laid down in the trade agreement at a later stage (O'Connor, 2012). O'Connor (2012), therefore, argues that negative listing should be favoured over positive listing, to prevent discrimination of innovative products.

5 Discussion

To answer the question: "*To what extent is the EU involved in the field of pre-hospital EMS and to what extent have the effects of this involvement on national pre-hospital EMS systems been studied in scientific literature?",* multiple aspects of this issue need to be addressed. First, the power of the EU as an institutions is discussed, to be able to gain insight into why they legislate in this specific area. In this section, a comprehensive overview of EU policies affecting pre-hospital EMS at the national level is created by discussing the choice of instruments used, together with the areas of pre-hospital EMS affected by these instruments. Second, the CETA is discussed and the effects this agreement can have on national pre-hospital EMS systems. Third, the coverage of the effects of EU authority instruments on national pre-hospital EMS systems in scientific literature is discussed. Last, the limitations of this study are discussed.

5.1 The EU's power in the field of pre-hospital EMS

Pre-hospital EMS is a field where, just as in healthcare in general, the EU does not have exclusive competence. Within this field, the EU is only allowed to play a supportive role. The nature of activities performed, as well as the components involved in the delivery of pre-hospital EMS, coincide with other areas where the EU does have competence, namely the single market. It is therefore not surprising that this policy area is used as the backbone of most of the authority instruments identified in this study. These authority instruments range from Treaty provisions, Regulations and Directives that are legally binding, to voluntary standards that are not. In table 3, an overview is given of the types of instruments found within this study.

Table 3. Overview of types of authority instruments identified

Types of instrument	**Nr. of identified instruments**	
Treaty provision	1	Legally binding
Convention	1	
Regulation	1	
Directive	3	
Decision	1	
ECJ Case law	7	
CEN Standard	9	Voluntary

5.1.1 Areas of pre-hospital EMS affected

When looking more closely at the identified instruments, it can be observed that almost all aspects that make up a national pre-hospital EMS system are affected by EU level legislation, as is shown in table 5 in appendix 2. The working times and movement of personnel working in pre-hospital EMS services, the equipment and vehicles used to deliver pre-hospital EMS, as well as the financing and establishment of pre-hospital EMS in certain regions are affected by EU legislation.

Particularly this last area of influence, the financing and establishment of pre-hospital EMS gave rise to some questions at national level, which led to multiple ECJ rulings. A total of seven cases were found, where the ECJ ruled on a subject that concerned or was related to pre-hospital EMS. All cases were related to the provision of pre-hospital EMS services and overall concerned the awarding of public service contracts and related issues. Within these cases, the ECJ gave clarification on the provisions laid down in EU legislation regarding public procurement, which was strikingly the only field of EU legislation that resulted in ECJ rulings on pre-hospital EMS.

The cases of the Commission of the European Communities vs. Ireland and the Commission of the European Communities vs. Germany gave an insight into the opinion of the Commission of the European Communities towards the power of the EU in the field of pre-hospital EMS. Both cases show that the Commission of the European Communities is in the opinion that the fundamental freedoms should be valued more than the autonomy of the member states to organise their pre-hospital EMS services. Both cases, however, gave rise to different rulings by the ECJ. In the case of Ireland, the arguments of the Commission of the European Communities were overruled by the ECJ, who were in the opinion that the arguments put forward by the Commission of the European Communities were not convincing in showing that Ireland failed to fulfil their obligations under Community regulations. This, however, does not mean that the stance taken by Commission of the European Communities was invalid, it only shows that no sufficient evidence was provided. In the case of Germany, the ECJ did rule that Germany failed to fulfil its obligations under Community regulations. However, whether the difference in outcomes between the two cases was due to a more convincing argumentation, or due to the other underlying conditions remains unclear.

Almost all identified instruments, with the exception of the technical standards and the council decision introducing a single European emergency call number, do not aim to legislate pre-hospital EMS systems specifically. The aim of these instruments is to regulate aspects of the single market, to which many element of a pre-hospital EMS system belong. This is in line with the findings of Greer (2006, p. 134), who argues that the EU has gained competence in the area of health, by *"changing the legal environment under which health systems contract employees, purchase goods, finance services, and*

organize themselves". This also implies that most of the identified legislation was not specifically designed for pre-hospital EMS systems, which can give rise to unforeseen consequences. These unforeseen consequences are discussed in further detail in section 5.1.3.

5.1.2 Choice of instrument

When looking at the types of instruments chosen, it can be observed that most of the identified instruments are legally binding, such as Treaties, Directives and Regulations. Only the CEN standards are voluntary and thereby not legally binding at member state level. This choice for legally binding instruments might seem surprising, taking into account the lack of competence in the area of pre-hospital EMS. However, seeing as it is not pre-hospital EMS specifically that is the focal point of the identified EU legislation but the single market, the choice for legally binding instruments can be explained.

Whenever the choice has to be made between a legally binding and a non-legally binding instrument, multiple factors need to be considered, from which subsidiarity, proportionality and conferral are explained in section 2.2. Seeing as all identified instruments have a legal base provided by the treaties, it can be assumed that the principle of conferral is thereby ensured. The principles of subsidiarity and proportionality are less clear and have a more subjective nature. It could be argued that the principle of subsidiarity has been ensured to a sufficient extent, as most of the identified authority instruments aim to legislate the single market, which falls under the EU's competence. The only legislation that does not have the single market as its focal point is the decision of the Council of the European Communities that introduced a single European emergency call number throughout the EU. In this case it could be argued that the introduction of a single emergency call number is more efficiently regulated at EU level than at member state level. Thereby, ensuring that the subsidiarity principle is taken into account in all identified authority instruments.

This leaves the principle of proportionality that needs to be considered, which refers to the content and form of EU action not exceeding what is necessary to reach its goals. With regard to this principle, the opinions differ whether the choice for legally binding instruments should be preferred over the alternative softer mechanisms. According to Trubek, Cottrell, and Nance (2005), legally binding instruments have the advantage that they tend to push towards uniformity, even though Directives have a certain freedom with regard to their application. Legally binding instruments can, however, only be used in areas where the EU has competence, which in areas such as pre-hospital EMS is not the case. This leaves the legislators at EU level with two options; legally binding instruments with a focal point in another policy area where competence can be found or non-legally binding instruments in the field of pre-hospital EMS.

This study showed that in a field such as pre-hospital EMS, legally binding instruments take a more prominent role than non-legally binding instruments, with competence to do so found in the policy area of the single market. According to Trubek et al. (2005), this might not always be a preferable situation, taking into account the positive effects that could be created using a "softer" approach to certain policy areas. Trubek et al. (2005) argue that to obtain an optimal result, it might even be necessary to transcend the choice between the so-called hard and soft law, by using hybrid forms where hard and soft mechanisms reinforce each other. The effectiveness of these "softer" or "hybrid" mechanisms have not yet been researched in the field of pre-hospital EMS.

5.1.3 Unforeseen consequences

The fact that the instruments identified were designed to legislate the single market in general and not pre-hospital EMS specifically, gives rise to some unforeseen consequences. Examples of these unforeseen consequences are put forward in the scientific literature on the EU working times directive. According to Cairns et al. (2008) the health sector will disproportionally be affected by the implementation of the EU working times directive. The authors put forward their worries regarding the continuity of care provision by training sufficient care professionals, as well as responding to a variable demand. Sectors that require a 24/7 service provision are hit the hardest and are expected to encounter the largest difficulties.

Studying the effects of EU legislation on national pre-hospital EMS systems can help identify these unforeseen consequences. By identifying them, lessons can be learned that can help legislators get insight into the unforeseen consequences in these vulnerable sectors. These insights can help them to make sure that specific sectors are not unnecessarily burdened with the introduction of new legislation.

5.2 External agreements with non-EU countries and national pre-hospital EMS systems

The example of CETA in this study, illustrated the effects a trade agreement between the EU and a non-EU country can have on pre-hospital EMS systems at the national level. Depending on how pre-hospital EMS services are organized at national level, they will either fall under the provisions of chapter 9 or not. A total of 15 member states decided to include reservations regarding pre-hospital EMS in a negative list. In general reservations were laid down regarding possible measures that could be taken to maintain a balance between supply and demand.

The possibility for Canadian pre-hospital EMS services to establish themselves in EU member states allows them to enter into the competition for calls for tender. This increased competition in the field of pre-hospital EMS could have both positive and

negative consequences. Whenever Canadian pre-hospital EMS would establish themselves in regions where shortages in supply can be found, the addition of new services are likely to have a positive effect by filling vacancies. Similar positive effects are to be expected in regions where the increased competition could lead to quality improvements and/or lower prices. Negative effects are to be expected in regions where supply is already in surplus. In these regions, an increase of competition is likely to make it more difficult for existing organizations to make a profit or break-even and thereby might threaten their existence.

As literature on the effects of external agreements such as CETA on pre-hospital EMS services is scarce, it is difficult to fully predict whether external agreements such as CETA mainly have positive effects or whether the negative effects prevail. The scarcity of literature will be further discussed in section 5.3. There are , however, some other aspects that need to be mentioned with regard to the external agreements between the EU and non-EU countries.

First of all it should be noted that within the CETA, the choice was made for negative listing, which implies that countries cannot add sectors to the list and exempt them from the rules laid down in this trade agreement at a later stage. It could therefore be argued that this could negatively affect future innovative sectors, which cannot be added to the negative list at a later stage. In addition, it should be noted that, as discussed in the Tögel Case, ambulance services consist of a transport element and a healthcare element. Depending on how countries described pre-hospital EMS in their negative listing, it might be possible that the transport element is still open to free trading. This could lead to some unexpected surprises at a later stage, when Canadian pre-hospital EMS services wishing to establish themselves in one of these countries, bring this issue before the ECJ. However, until such a case has been brought before the ECJ, no definitive answer can be given to what the exact consequences of the Tögel case will be for CETA.

Second it should be noted that every agreement is negotiated separately, which makes it impossible to generalize from CETA to other agreements. It is to be expected that countries which included reservations within CETA are likely to include similar reservations in other trade agreements. However, to be able to get a more comprehensive overview of the overall effects of trade agreements, more agreements should be analysed and studied.

5.3 Coverage within scientific literature

Overall, limited scientific literature was found that focused on the effects that EU authority instruments have on national pre-hospital EMS systems. Some literature was identified that focused on the effects of these authority instruments on healthcare in

general. Research more specifically on the effects of these instruments on national pre-hospital EMS systems is lacking.

Seeing that some legislation such as the public procurement directive were only implemented recently, it is not surprising that in these areas little scientific literature can be found on the effects at the national level. The rules laid down in Directive 2014/24/EU had to be transposed in 2016, which gives very limited time for scientific studies on the effects at national level to be conducted and published. For other legislation, such as Regulation 883/2004, which laid down rules for the reimbursement of emergency medical care when abroad and Directive 2003/88/EC laying down rules regarding working times, were implemented more than a decade ago, which should have given sufficient time for studies to be conducted and published.

More research in this field is therefore needed, especially as laws not specifically designed for this sector have quite a large effect. As discussed in section 5.1, almost all of the authority instruments that were identified do not specifically aim to affect national pre-hospital EMS systems. It would therefore be particularly interesting and beneficial to study what these unforeseen consequences could be. Literature on the working times directive already suggests that sectors such as pre-hospital EMS, that need to keep their services operational 24/7, might experience problems with the introduction of these rules. However, to get a clear picture of the actual effects of these authority instruments, more research is needed.

5.4 Limitations

The first limitation of this study is the choice to only include English sources within this scoping review. For the selection of EU instruments, this should not be seen as a limitation, as these are all available in English and multiple other languages. For the literature search, this should be seen as a limitation. By only searching for English literature, all national literature written in the native language of the member state are hereby excluded. This had multiple reasons, with the language skills of the researcher being the most prominent one. When this study would be conducted again, it would be advisable to include multiple researchers and thereby broadening the scope of languages that could be included in the search. It would be possible that effects of EU legislation on national pre-hospital EMS systems is published in the native language of the member states, which in this study were not identified.

Another limitation of this study is the non-systematic approach that was taken to the search for authority instruments and literature. However, taking into account the limited timeframe available for this study and the broad scope of this field of research, a non-systematic approach was the only feasible option. It would still be advisable that based

on these findings a more systematic search would be performed in each identified field of influence, to ensure that all relevant literature is found.

The last limitation of this study is that only a single external agreement was chosen to serve as an example of external agreements concluded between the EU and non-EU countries. Again, taking into account the limited timeframe that was available for this study, this was the only feasible option. This, however, does not mean that different findings would have resulted from the choice for another or multiple external agreements. It would therefore be advisable that future studies include at least more than one external agreement, to see whether the effects on pre-hospital EMS systems differ between external agreements or whether they are the same.

6 Conclusion

A total of 7 areas of influence were found, where EU legislation has an effect on national pre-hospital EMS systems. The majority of instruments identified are legally binding and almost all aspects of national pre-hospital EMS systems are affected. CETA can also affect national EMS systems, by opening up the market for Canadian pre-hospital EMS services. Canadian EMS services could establish themselves in EU member states, which allows them to enter into the competition for calls for tender. This makes the influence of the EU far-reaching when it comes to national pre-hospital EMS systems, even though the EU's competence in this specific policy field is limited. Their far reaching influence can be explained by the fact that most of the identified authority instruments, as well as CETA were concluded with the single market as their focal point, not pre-hospital EMS systems specifically.

The coverage of this theme in the scientific literature is very limited. Only few studies have been conducted looking at the effects of EU legislation, ECJ rulings or external agreements on health systems, with even less studies focusing on national pre-hospital EMS systems. This lack of scientific research makes it difficult to evaluate the consequences of this EU level action on national pre-hospital EMS systems. It is, therefore, important that more research will be conducted in this area, especially given the fact that the EU legislation affecting national pre-hospital EMS systems are not specifically designed for these systems. Research in this field could shed light on the unforeseen consequences that arise, which could help legislators take this into account in the future.

In addition, it might be advisable that in light of the proportionality principle, legislators explore alternative options of legislation that do not unnecessarily burden sectors such as pre-hospital EMS. This could be done by either estimating the unforeseen effects on sectors that need to be operational 24/7 or by making use of alternative legislative mechanisms, including soft law and hybrid mechanisms.

Overall, it can be concluded that the EU has a far reaching influence in the field of pre-hospital EMS, with most of the legislation affecting national pre-hospital EMS systems having the single market as a focal point. Research looking at the effects this EU legislation has on national pre-hospital EMS systems is insufficient and lacking in many areas. It would therefore be recommendable to promote research initiatives in this area that could use this study as a starting point to identify areas of influence. In addition, it would be advisable to look at other policy instruments used by the EU, including nodality, treasure and organization instruments. This would give a complete and comprehensive overview of the instruments used by the EU that could affect national pre-hospital EMS systems.

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Appendix 1 – Search strategy for literature search per area of EU involvement

In table 4, an overview can be found of the search terms used to search for literature per area of EU involvement.

Table 4. Search terms used per area of involvement

Area of involvement	Search terms used
Single European emergency call number	"EU" AND "single emergency call number" OR "112"
Working times	"working time directive" OR "Directive 2003/88/EC" AND "ambulance" OR "dispatch centre" OR "EMS" OR "emergency medical care"
Technical requirements for pre-hospital EMS	"road ambulances" OR "air ambulances" AND "CEN standard" OR "technical requirements" AND "EU"
Free movement of professionals	"free movement" AND "professionals" AND "EMS" OR "emergency medical care" OR "dispatch centre"
Cross-border collaboration	"cross-border collaboration" AND "ambulance" OR "EMS" OR "dispatch centre" AND "EU" OR "Europe"
Financing of EMS – a cross-border perspective	"Regulation 883/2004" AND "ambulance" OR "EMS" OR "emergency medical care"
Public procurement	"public procurement" AND "ambulance" OR "dispatch centre" OR "EMS" OR "emergency medical care"
CETA	"CETA" AND "ambulance" OR "dispatch centre" OR OR "EMS" OR "emergency medical care"

Appendix 2 – Overview of EU instruments affecting national pre-hospital EMS systems

In table 5, an overview can be found of the identified EU instruments that affect national pre-hospital EMS systems.

Table 5. Overview of EU instruments affecting national pre-hospital EMS systems

Title	Topic	Type of instrument	Part of the EMS system affected
Council decision of 29 July 1991 on the introduction of a single European emergency call number	Single European emergency call number - 112	Decision (legally binding)	way to contact the dispatch centre
Directive 2003/88/EC of the European Parliament and of the Council of 4 November 2003 concerning certain aspects of the organisation of working time	Working times	Directive (legally binding)	personnel working in dispatch centres and ambulance services
EN 1789:2007+A2:2014 Medical vehicles and their equipment - Road ambulances	road ambulance requirements	Standard (not legally binding)	vehicles used in EMS
EN 13718-1:2014 Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances	air ambulance requirements	Standard (not legally binding)	vehicles used in EMS
EN 13718-2:2015 Medical vehicles and their equipment - Air ambulances - Part 2: Operational and technical requirements for air ambulances	air ambulance requirements	Standard (not legally binding)	vehicles used in EMS
EN 1865-1:2010+A1:2015 Patient handling equipment used in road ambulances - Part 1: General stretcher systems and patient handling equipment	equipment for road ambulances	Standard (not legally binding)	equipment used in EMS
EN 1865-2:2010+A1:2015 Patient handling equipment used in road ambulances - Part 2: Power assisted stretcher	equipment for road ambulances	Standard (not legally binding)	equipment used in EMS
EN 1865-3:2012 Patient handling equipment used in road ambulances - Part 3: Heavy duty stretcher	equipment for road ambulances	Standard (not legally binding)	equipment used in EMS

EN 1865-4:2012 Patient handling equipment used in road ambulances - Part 4: Foldable patient transfer chair	equipment for road ambulances	Standard (not legally binding)	equipment used in EMS
EN 1865-5:2012 Patient handling equipment used in road ambulances - Part 5: Stretcher support	equipment for road ambulances	Standard (not legally binding)	equipment used in EMS
EN 794-3:1998+A2:2009 Lung ventilators - Part 3: Particular requirements for emergency and transport ventilators	lung ventilators used during emergencies and transport of patients	Standard (not legally binding)	equipment used in EMS
Treaty on the functioning of the European Union (TFEU) – article 45	Freedom of movement of professionals	Treaty (legally binding)	personnel working in EMS
Directive 2013/55/EU of the European Parliament and of the Council of 20 November 2013 amending Directive 2005/36/EC on the recognition of professional qualifications and Regulation (EU) No 1024/2012 on administrative cooperation through the Internal Market Information System ('the IMI Regulation')	Recognition of professional qualifications	Directive (legally binding)	qualifications of personnel working in EMS
European Outline Convention on Transfrontier Co-operation between Territorial Communities or Authorities	Cross-border collaboration	Convention (legally binding)	cross-border collaboration between EMS services
Regulation 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems	Financing of cross-border emergency care	Regulation (legally binding)	Financing of EMS services
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC	Public procurement	Directive (legally binding)	Tenders for public contracts in the field of EMS

Appendix 3 – Reservations per member state included in CETA

In table 6, an overview is given of which member states included reservations within the CETA and which member states didn't .

Table 6. Reservations per member state included in CETA

EU Member State	Reservation
Croatia	"Establishment of some privately funded social care facilities may be subject to needs based limits in particular geographical areas" (European Union & Canada, 2016, p. 1028).
France	"For hospital and ambulance services, residential health facilities (other than hospital services) and social services, an authorisation is necessary in order to exercise management functions. The authorisation process takes into account the availability of local managers" (European Union & Canada, 2016, p. 1068).
Germany	"Rescue services and "qualified ambulance services" are organised and regulated by the Länder. Most Länder delegate competences in the field of rescue services to municipalities. Municipalities are allowed to give priority to not-for-profit operators. This applies equally to foreign as well as domestic service suppliers. Ambulance services are subject to planning, permission and accreditation" (European Union & Canada, 2016, p. 1081).
Austria	"Austria reserves the right to adopt or maintain any measure with respect to the supply of privately funded ambulance services" (European Union & Canada, 2016, p. 1318).
Belgium	"Belgium reserves the right to adopt or maintain any measure with respect to the supply of privately funded ambulance and residential health services other than hospital services" (European Union & Canada, 2016, p. 1320).
Bulgaria	"Bulgaria reserves the right to adopt or maintain any measure with respect to the supply of privately funded hospital, ambulance, and residential health services other than hospital services" (European Union & Canada, 2016, p. 1335).
Cyprus	"Cyprus reserves the right to adopt or maintain any measure with respect to the supply of privately funded hospital, ambulance, and residential health services other than hospital services" (European Union & Canada, 2016, p. 1343)

Czech Republic	"The Czech Republic reserves the right to adopt or maintain any measure with respect to the supply of privately funded hospital, ambulance, and residential health services other than hospital services" (European Union & Canada, 2016, p. 1349)
Finland	"Finland reserves the right to adopt or maintain any measure with respect to the supply of privately funded hospital, ambulance, residential health services other than hospital services, and other human health services" (European Union & Canada, 2016, p. 1364)
Hungary	"Hungary reserves the right to adopt or maintain any measure requiring the establishment or physical presence in its territory of suppliers and restricting the cross-border supply from outside its territory of all hospital, ambulance, and residential health services other than hospital services, which receive public funding" (European Union & Canada, 2016, p. 1391)
Malta	"Malta reserves the right to adopt or maintain any measure with respect to the supply of privately funded hospital, ambulance, and residential health services other than hospital services" (European Union & Canada, 2016, p. 1415)
Poland	"Poland reserves the right to adopt or maintain any measure with respect to the supply of ambulance services" (European Union & Canada, 2016, p. 1421)
Slovak Republic	"The Slovak Republic reserves the right to adopt or maintain any measure with respect to the supply of privately funded hospital, ambulance, and residential health services other than hospital services" (European Union & Canada, 2016, p. 1433)
Slovenia	"Slovenia reserves the right to adopt or maintain any measure with respect to the supply of privately funded ambulance services" (European Union & Canada, 2016, p. 1439)
United Kingdom	"The United Kingdom reserves the right to adopt or maintain any measure with respect to the supply of privately funded ambulance services and residential health facilities services other than hospital services" (European Union & Canada, 2016, p. 1451)