



Study on Enhancing implementation of the Cross- Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU

Mapping and Analysis of Prior-authorisation lists:
analytical report



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Study on Enhancing implementation of the Cross- Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU

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Glossary

- Directive: 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;
- EU: European Union;
- MS: Member State;
- NCP: National Contact Point;
- PA: Prior-authorisation;
- SAI: Specific Analytical Item.

Summary

Background

The European Commission Directorate-General for Health and Food Safety (DG SANTE) has commissioned ECORYS Nederland B.V., Technopolis and Spark Legal Network to conduct a study to enhance the implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU. One of the aims of the study is to develop Guiding Principles that will serve as a recommendation for streamlining and simplifying prior-authorisation (PA) systems across Member States (MS). For that purpose, data was collected and analysed to answer the following two research questions:

1. How is prior-authorisation applied in the Member States and EEA EFTA countries?
2. What are the underlying reasons for the different prior-authorisation approaches in the Member States and EEA EFTA countries?

This report presents the answers to these research questions and served as background information for the virtual workshops organised on 11 and 12 March 2021. The aim of these workshops was to validate and discuss the presented results, as well as to have an exploratory interactive discussion on how to streamline and simplify PA across MS. After the workshop was conducted, a separate workshop report was shared with the participants. The current analytical paper was updated with the most important insights and reflections that were discussed during the workshop.

Data collection

We developed a mapping tool in order to map the PA-systems that are in place in MSs and EEA EFTA countries that includes the following key topics:

1. Characteristics of the PA-system in place;
2. Comprehensiveness of information on PA;
3. Comprehensibility of information on PA;
4. Consistency of information on PA.
5. Underlying reasons for the PA-system in place.

The mapping tool was populated with data collected via desk and field research for all 27 MSs and 3 EEA EFTA countries. For each key topic, several Specific Analytical Items (SAIs) were developed. With regard to the topics comprehensiveness and comprehensibility of information provision on PA, a scoring system was developed to rate the available information per SAI on a 1-4 point scale, with 1 being the lowest and 4 being the highest. For both comprehensiveness and comprehensible a separate total score was determined, ranging from 2.5 (minimum score) and 10 (maximum score). This was a weighted score, for which the number of received points was divided by the total number of points that could be obtained, multiplied by 10.

It is important to note that the results regarding comprehensiveness and comprehensibility, are primarily based on the results of our website analysis. Subsequently, these results were validated during the interviews and we provided MSs with the opportunity to complement our findings.

Results

1. Characteristics of the PA-systems in place

Most MSs (20) and one EEA EFTA countries have chosen to implement a PA-system. For one EEA EFTA country it remained unclear, based on Member State data on cross-border mobility with information on prior authorisation of 2017 this country was considered as

having a PA-system. The way it is implemented differs greatly across countries. Although MSs based their legislation on one or more of the criteria for PA that are listed in Article 8 of the Directive, countries made different choices in how this is translated to a *PA-list*. MSs are obliged to make the health services that are subject to PA publicly available on a detailed and sufficiently defined shortlist, but it was observed that 5 MSs and one EEA EFTA country only refer to general criteria on their PA-lists. One MS refers to general criteria and included a list of examples of treatments that meet a certain criteria but leaving the list unexhausted. For the remaining 14 MSs (for one state it remained unclear), PA-lists are developed that specify for which actual treatment and/or medical equipment PA is required, but the content of the PA-lists differs significantly, ranging from 6 to 180 separate items. Hence, on the one hand, MSs have developed very general and broad PA-lists, while on the other hand other MSs have drawn up an extensive list of treatments.

The *procedure for requesting PA* differs across MSs in which PA is implemented. Citizens need to request for PA via an application form, along with other (medical) documents and the different application forms and documents are, in most cases, examined by competent national authorities. In some of the analysed MSs the national health insurer or regional authorities examine the PA-requests. The *maximum time period for PA-requests to be dealt with* ranges between 5 and 60 days, although some MSs have speed procedures available in case urgent care abroad is required. In most MSs, there is not a procedure in place for retroactively authorising PA and granting reimbursement in individual cases if PA was not issued prior before the treatment. In five MS a procedure to retroactively authorise PA is in place for individual urgent or emergency situations, in which it can be proven that PA could not be obtained within a sufficient amount of time.

2. Comprehensiveness of information in MSs with PA-system

Comprehensive information is needed for patients to make a well-considered decision regarding cross-border healthcare. First, patients should have access to information that clarifies the *differences between EU Regulation 883/2004 and the EU Directive 2011/24/EU*; 9 MSs provided this information in a general way. 5 MSs also provided information that explains that in case the conditions laid down in Regulation are met, the PA will be granted in accordance with that Regulation, which is generally more favourable for the patient. In addition, 4 MSs point out to patients' rights under the Directive when PA is refused under the Regulation or that they assess whether PA could be issued under the Directive when PA is refused under the Regulation. Furthermore, patients should have access to a clear explanation of *whether a PA-system as defined by the Directive is in place and what the PA-procedure looks like*. It was observed that 17 MSs and one EEA EFTA country describe the procedure for PA on their websites. Hence, for 4 MSs and 1 EEA EFTA country the PA procedure was not outlined on the website. Subsequently, it should be clear for which treatments and/or medical equipment PA is required and thus whether a PA-list is in place. According to our analysis, for those MSs with a PA-system, in 16 MSs, it is clear that a PA-list is in place. Furthermore, in case PA is required for certain treatments, the accessibility of the PA-list was assessed and it was observed that, of those MSs that have a PA-system, in total 15 MSs provide the PA-list on their NCP website.

3. Comprehensiveness of information in MSs without PA-system

Also for MSs without a PA-system, patients should have access to information that clarifies the differences between EU Regulation 883/2004 and the EU Directive 2011/24. 3 MSs without PA provide this information in a general way. None of the MSs without a PA-system provided information that in case the conditions laid down in the Regulation

883/2004 are met, PA might be granted and costs reimbursed in accordance with that Regulation on their websites, and only 1 MS representative indicated in the interview that they provide this information to patients when they request this information. 3 MSs without PA stated that they provide information about patients' rights under the Directive when PA is refused under the Regulation or that they assess whether PA could be issued under the Directive. In case MSs have not implemented a PA-system, it could still be helpful for patients to have a clear explanation of whether PA is in place. Four MSs state on their NCP website that PA is not required when seeking healthcare in another MS under the Directive.

4. Comprehensibility of information for MSs with PA-system

Presenting comprehensible information will mitigate the risk of patients being excluded or deterring patients from seeking healthcare in another country. In total, 17 MSs and one EEA EFTA country provided information in English in addition to the native language, and 2 MSs provided in a third language. 4 MSs provide the information only in the native language. 7 MSs and 1 EEA EFTA country had options available for people with decreased sensory functioning (visual). Furthermore, we analysed whether general information on PA was easy to find. For most MSs (14) it was determined that the information was easy to find, for example because a separate header or section for PA was available on the website. For 5 MSs and 1 EEA EFTA country, the information was received as moderately easy to find and for 2 MSs and 1 EEA EFTA country it was perceived as difficult to find. It was also assessed whether general information on PA was provided in laymen terms and information was considered as easy to understand for 9 MSs. For 2 MSs it was perceived as complex and unclear, for the remaining MSs/EEA EFTA countries it was perceived as moderately clear. Furthermore, of those MSs that have implemented PA, the PA-list itself was defined as easy to understand for 12 MSs and the PA-procedure for 9 MSs.

5. Comprehensibility of information for MSs and EEA EFTA countries without a PA-system

With regard to language, seven MSs and one EEA EFTA country without PA, provided information in English in addition to the native language(s). Five MSs without PA had options available for people with decreased sensory functioning, of which most had the option to increase the text size. We also determined whether information on PA was easy to find for those MSs that do not have a PA-system. Four MSs and one EEA EFTA country provided easy access to information on PA, one MS scored moderately and one was scored as not easy to find. Two MSs without a PA-system provided information on PA that was easy to understand, three MSs were perceived as moderately clear, three MSs/EEA EFTA countries were assessed as providing unclear information.

6. Consistency of information

For both MSs with a PA-system in place and MSs without such a system, it is important that the information on PA is consistent. Most MS representatives indicate that they are not aware of any inconsistencies. In general it was observed that the extent to which *coordination and communication* with regard to the Directive takes place, depends on how the different organisations are structured. In some MSs, NCPs are intertwined with health insurers, in other MSs, NCPs are organised outside the system and may function as the 'watchdog' for health insurers and health care providers. With regard to information on the PA-procedure and content of the PA-list, it was observed that in most MSs that have implemented PA, there is little to no coordination and communication between the competent body and other stakeholders on this specific topic.

7. Underlying reasons for (not) having a PA-system

The reasons for (not) having a PA-system differ across MSs. With regard to having a PA-list in place, MS representatives indicated that the *protection of their healthcare system* is the main reason for the implementation of a PA-system. In line with this, some MSs explained that it was a *political decision* to introduce the PA-system. At the time the Directive was implemented, the effect on MSs' healthcare systems was uncertain and for some MS, the introduction of a PA-system served as a means to monitor the effect of the Directive on own healthcare systems. Other reasons for having a PA-system that were mentioned include: 1) providing patients with the certainty of insurance coverage; 2) alignment with the national healthcare system. 7 MSs and 1 EEA EFTA country do not have a PA-system in place. The main reasons for not having implemented or removed of the PA-system is related to a lack of need for such a system. In turn, this reason for this lack of need was mainly related to a (expected) limited number of PA-requests, or a lack of financial threat to the healthcare system.

Further steps

The current mapping exercise shows that there is still room for improvement with regard to information provision on prior-authorisation under the Directive. The next step of our study is therefore, to develop Guiding Principles for streamlining and simplifying prior-authorisation lists so as to make them more accessible, transparent and understandable to patients.

1 Introduction

In March 2011, the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (hereafter the Directive) was adopted.¹ The Directive clarifies the rights of patients to seek reimbursement for healthcare received in another Member State (MS) and ensures that these rights can be used in practice. It provides a framework for cross-border healthcare and 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."²

1.1 Prior-authorisation

The Directive sets out the conditions under which a patient may seek healthcare in another MS and when patients have the right to reimbursement of the costs by the MS of affiliation. At a national level, decisions are made about the healthcare basket to which citizens are entitled and the related financial mechanisms.³ Before implementation of the Directive, the so-called Social Security Regulations were in place to regulate reimbursement in case healthcare costs were borne in another MS.

Although in general no PA should be required under the Directive, MSs could opt for such a system and many MSs have done so. If such a system is in place, patients should request PA from the MS of affiliation before utilising healthcare in another MS. According to Article 8(2) of the Directive, PA is limited to healthcare that is subject to certain conditions. The list in Article 8(2) is exhaustive and is limited to:

- healthcare treatments that require at least one night in the hospital and/or the use of expensive specialised medical equipment or infrastructure;
- safety-risk for the patient or the population;
- treatment provided by a healthcare provider that could give rise to serious and specific concerns relating to quality or safety.

If MSs consider PA necessary, they are obliged to make the health services that are subject to PA publicly available on a detailed and sufficiently defined shortlist.⁴ It should thus be clear and publicly available to which treatments this applies and what the underlying criteria are to include these treatments on the prior-authorisation list. Authorisation may not be refused in case the patient is entitled to the treatment in the MS of affiliation and the patient cannot receive the treatment in their own MS within a medically justifiable time limit.⁵

In Annex A. Legal Context, more information on the Social Security Regulations, the Directive and the differences between the Regulations and Directive can be found.

¹ 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.

² Directive 2011/24/EU, recital 10.

³ Directive 2011/24/EU, recital 5.

⁴ Directive 2011/24/EU, art. 8(7).

⁵ Directive 2011/24/EU, art. 8(5).

1.2 Research questions

Previous studies on the Cross-border Healthcare Directive showed that information on the treatments for which patients should request PA is not always sufficient.⁶ This may result in patients not knowing which health services are subject to PA and, subsequently, a limited number of individuals requesting prior authorisation when they seek cross-border healthcare.

The European Commission Directorate-General for Health and Food Safety (DG SANTE) has commissioned ECORYS Nederland B.V., Technopolis and Spark Legal Network to conduct a study to enhance the implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU. One of the aims of this study is to develop Guiding Principles that will serve as a recommendation for streamlining and simplifying PA systems across MSs. For that purpose, first the following research questions were answered:

1. How is Prior-authorisation applied in the Member States and EEA EFTA countries?

What are the underlying reasons for the different Prior-authorisation approaches in the Member States and EEA EFTA countries?

In the following chapter, Chapter 2, we will elaborate on data collection. Thereafter, in Chapter 3, we will present the results of our mapping exercise. The report served as background information for the virtual workshop that was organised on 11 and 12 March 2021. The aim of this workshop was to validate and discuss the results of the mapping, as well as to have an exploratory interactive discussion on how to streamline and simplify prior-authorisation across Member States. After the workshop was conducted, a separate workshop report was shared with the participants. The current analytical paper was updated with the most important insights and reflections that were discussed during the workshop.

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⁶ Evaluative Study on the cross-border healthcare Directive (2011/24/EU), 2015, http://ec.europa.eu/health/sites/health/files/cross_border_care/docs/2015_evaluative_study_frep_en.pdf.

⁷ 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.

⁸ Directive 2011/24/EU, recital 10.

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Although in general no PA should be required under the Directive, MSs could opt for such a system and many MSs have done so. If such a system is in place, patients should request PA from the MS of affiliation before utilising healthcare in another MS. According to Article 8(2) of the Directive, PA is limited to healthcare that is subject to certain conditions. The list in Article 8(2) is exhaustive and is limited to:

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If MSs consider PA necessary, they are obliged to make the health services that are subject to PA publicly available on a detailed and sufficiently defined shortlist.¹⁰ It should thus be clear and publicly available to which treatments this applies and what the underlying criteria are to include these treatments on the prior-authorisation list. Authorisation may not be refused in case the patient is entitled to the treatment in the MS of affiliation and the patient cannot receive the treatment in their own MS within a medically justifiable time limit.¹¹

In Annex A. Legal Context, more information on the Social Security Regulations, the Directive and the differences between the Regulations and Directive can be found.

1.4 Research questions

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⁹ Directive 2011/24/EU, recital 5.

¹⁰ Directive 2011/24/EU, art. 8(7).

¹¹ Directive 2011/24/EU, art. 8(5).

¹² Evaluative Study on the cross-border healthcare Directive (2011/24/EU), 2015, http://ec.europa.eu/health/sites/health/files/cross_border_care/docs/2015_evaluative_study_frep_en.pdf

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2 Data collection

Our approach for collecting the data necessary to answer research questions 1 and 2 consists of the following three consecutive steps:

- Developing a mapping tool;
 - Conducting a desk study; and
 - Conducting field research.
- Each of these elements is further elaborated on in this chapter.

2.1 Mapping tool

We developed a mapping tool in order to map the PA systems that are in place in MSs and EEA EFTA countries that includes the following key topics:

1. Characteristics of the PA-system in place;
2. Comprehensiveness of information on PA;
3. Comprehensibility of information on PA;
4. Consistency of information on PA;
5. Underlying reasons for the PA-system in place.

For each key topic, several Specific Analytical Items (SAIs) were developed. With regard to the topics comprehensiveness and comprehensibility of information provision on PA, a scoring system was developed to rate the available information per SAI on a 1-4 point scale, with 1 being the lowest and 4 being the highest. For both comprehensiveness and comprehensible a separate total score was determined, ranging from 2.5 (minimum score) and 10 (maximum score). This was a weighted score, for which the number of received points was divided by the total number of points that could be obtained, multiplied by 10. More detailed information on the number of SAIs for both topics is provided in the result section.

2.2 Desk study

In order to populate the mapping tool, we conducted a desk study. The starting points for our desk study were the individual NCP websites. On these websites the information regarding PA per MS and EEA EFTA country should be available and we registered whether or not PA-lists are in place, and if yes, which information was available regarding these lists. In addition, we consulted the Commission's annual report on cross-border mobility with information on prior authorisation (e.g., numbers of approval, refusal and reasons for refusal) (year 2019).

The desk study was performed between December 2020 and February 2021, by two trained researchers using a data collection template (i.e., the mapping tool). Data were collected using general websites on cross-border healthcare, as well as specific websites dedicated to prior-authorisation (see Annex B for all URLs). On average our website analysis took 1.5 hour or more per website to complete the data collection and fill in the mapping tool. We would expect patients to be less trained and experienced in finding information on the NCP websites than our researchers, and therefore less proficient. Any information which could not be found by our researchers would thus conceivably also not be found by the average patient.

2.3 Field research

In order to validate the desk study on completeness and accuracy, we requested MS representatives to participate in bilateral exchanges via email or interviews. Furthermore, when necessary, we requested translations or additional information in case it was not found on the website (for example with regard to information on the PA-list) during these exchanges. Field research was also deemed necessary in order to gain insight into underlying reasons or in-depth information on the PA-systems in place.

If the MS's representative was willing to participate in an interview, a semi-structured interview was conducted according to an interview guide that was based on our mapping tool (Annex C). At time of writing of the current report, 23 MSs participated in an interview. Three MSs responded to the interview questions via email. One EEA EFTA country declined the request to participate and for the remaining four MSs interview questions were sent and we were awaiting a response to these questions. Hence, for these later MSs the results from our desk study were not validated or complemented via bilateral exchanges.

2.4 Workshop

In order to validate and discuss the results of the mapping, a 2 half-day virtual workshop was organised on March 11 and 12. The general objectives of the workshop were to:

1. Present and validate the results of the mapping of PA-lists;
2. Have an interactive discussion on the results of the mapping of PA-lists;
3. Have an exploratory interactive discussion on how to streamline and simplify PA-lists across Member States.

Annex D provides an overview of the programme. A total number of 44 participants covering 25 MSs and EEA EFTA countries attended the workshop. Not all participants attended both days of the workshop: 42 participants attended the workshop on day 1; 39 participants attended the workshop on day 2. Five MSs/EEA EFTA countries were not represented at the workshop. After the workshop was conducted, a separate workshop report was shared with the participants. The current analytical paper was updated with the most important insights and reflections that were discussed during the workshop.

3 Results

In the following paragraphs the results of our mapping exercise are presented. First, we present the results on how prior-authorisation is applied, including information on the characteristics of prior-authorisation systems and information provision on prior-authorisation to patients. Thereafter, we elaborate on the underlying reasons of Member States (MSs) for having (not) implemented a PA-system. Individual MS mapping results are provided in Annex E.

3.1 How is prior-authorisation applied?

3.1.1 Characteristics of prior-authorisation systems

To gain insight into how PA is applied across MSs and EEA EFTA countries, we first assessed the state of play as to whether Member States and EEA EFTA countries have a PA-system in place as defined by the Directive. Furthermore, if a PA-system is implemented, we gathered information on the criteria under which PA should be issued or refused, the implementation of PA-lists, the procedures for requesting PA and information related to the number of PA requests and refusals.

Implementation of PA-systems

During the analysis it was noted that the system of prior authorisation was implemented differently among member states, which makes it difficult to compare across MSs. It was observed that 18 MSs have clearly adopted a PA-system as described under the Directive and 6 MSs clearly have not implemented a PA-system or decided to remove it. One EEA EFTA country has implemented a PA-system, one EEA EFTA country does not have a PA-system and for one EEA EFTA country it remains unclear from our website analysis whether a PA system was in place, for which, due to unavailability of the country's representative, we were unable to clarify this. Based on the Commission's annual report on cross-border mobility with information on prior authorisation of 2017 this country was considered as having a PA-system.

For three MSs it is less clear whether they have a PA-system as described under the Directive in place. One MS has a PA-system in place, yet requesting PA is recommend however, and not mandatory in the MS. One MS has implemented one PA-system for both the Directive and Regulation. In this MS the patient follows one unique procedure and it is then decided by the competent authority whether PA will be granted under the Regulation or the Directive. However, similar criteria for PA to be granted under the Directive or Regulation are used. In the result section these MSs are listed in the category 'MSs with PA'. One MS officially does not have a PA-system, but PA is required by the healthcare insurers. This MSs is listed under the category 'MSs without PA'.

We observed many differences between MSs regarding the way PA is implemented, although most MSs adopted one or more of the criteria for PA that are described in the Directive (additional criteria for PA were hence not observed in our analysis:

- 15 MSs implemented PA for the use of expensive specialised medical equipment or infrastructure;
- 9 MSs implemented PA for treatments that involve a safety risk for the patient or the population;
- 9 MSs implemented PA for a treatment provided by a healthcare provider that could give rise to serious and specific concerns relating to quality or safety;
- 17 MSs implemented PA for treatments that requires an overnight stay.

If MSs consider PA necessary, they are obliged to make the health services that are subject to PA publicly available on a detailed and sufficiently defined shortlist (i.e., PA-list).¹³ It should be publicly available and clear, in particular to patients, for which treatments PA applies and what the underlying criteria are to make these treatments subject to PA. The PA-list should thus provide patients with more detail than the overall criteria for PA as outlined in the Directive.

Overall, it was observed that 5 MSs and one EEA EFTA country refer to the above mentioned general criteria, not providing any specific treatments and/or medical equipment on their lists. One MS refers to general criteria and included a list of examples of treatments that meet a certain criteria but leave the list unexhausted. For the remaining 14 MSs, there are exhaustive PA-lists available that specify for which actual treatments and/or medical equipment PA is required:

- 10 MSs have developed PA-lists specified for treatments and medical equipment;
- 4 MSs have developed PA-lists specified only for certain medical equipment.

The PA-lists differ significantly in the extent to which the treatments and/or medical equipment are further specified and the number of treatment and/or medical equipment that are included on the list ranges from 6 to 180 separate items.

With regard to PA for treatments that requires an overnight stay, none of the 16 MSs that have implemented this criteria, have specified for which treatments this actually applies. The reasons for not specifying this was discussed during the workshop and one of the reasons is that it differs per patient (e.g., due to age) whether a certain treatment requires an overnight stay. Furthermore, it was discussed that it differs per MS and, some MSs determine whether PA is required based on whether the treatment requires an overnight stay in the MS of affiliation, while other MSs decide whether PA is required based on whether the treatment requires an overnight stay in the MS of treatment.

Prior-authorisation procedures

Also the procedure for requesting PA differs across MSs in which PA is implemented. In all MSs where PA is required, citizens need to request for PA via an application form, which should be filled in along with other (medical) documents, such as:

- Copy of ID;
- Doctor referral;
- Current health status;
- Medical diagnosis/indication;
- Medical certification;
- Reason for treatment;
- Specification of type of treatment;
- Desired treatment goals;
- Dates available for appointments;
- The healthcare provider and/or country and/or facility of treatment;
- Price estimation.

In most MSs, the different application forms and documents are examined by the competent national authority and/or regional authorities. In most MSs, application forms can be handed online (e.g., via email, application websites etc.), while in some MSs written PA requests are required. In five MSs regional authorities or health insurance companies do handle the PA applications. During the workshop, some of these MSs

¹³ Directive 2011/24/EU, art. 8(7).

indicated that they were not able to place an application form on their national website, since the insurance companies or regional authorities use their own forms. One of these MSs has placed an example of the application form on their national website to inform patients where and what information they can find on the website of the regional authorities.

The maximum processing times relating to PA requests differ across MSs from 14 days, 15 days, 27 days, 30 days, 40 days (EL) 45 days (ES), 60 days (HR, SI), 66 days (BG) to 90 days (PT). In two MSs, there is no maximum time period for PA requests, but these MSs mentioned that all requests are dealt with within 2 or 3 days and 5 days. Compared to the annual report of the European Commission, it was noticed that one MS (30 days literature, 15 days website) has included lower maximum processing times on their website than reported in the annual report. One MS (60 days literature and 30 days interview) reported a lower maximum processing time during the interview. Additionally, 4 MS representatives mentioned in the interviews that the maximum application processing time does not apply for planned urgent care abroad; when this applies these MSs deal with the PA-request in 1 day, 3 days, 5 days or 15 days.

In most MSs there is not a procedure in place for retroactively authorising PA and granting reimbursement in individual cases if PA was not issued prior before the treatment. In four MSs, a procedure to retroactively authorise PA is only in place for individual urgent or emergency situations, for which it can be proven that PA could not be obtained within a sufficient amount of time.

Prior-authorisation requests and refusals

The numbers of PA requests that are received, refused, accepted, and withdrawn were mapped via bilateral contact with MSs and validated through the MS data on cross-border patient healthcare following Directive 2011/24/EU Year 2019.

In the 2019 annual report of the European Commission, MSs reported that a total of 7,171 requests for PA under the directive were received. Of those MSs having PA¹⁴, 13 MSs, reported having fewer than 100 requests. Overall, 78% (n = 5,637) of the PA requests were authorised, 16% (n = 1,131) were refused, 5% (n = 343) were withdrawn and 1% (n = 60) was unaccounted for. These percentages can be misleading, since no significant pattern was discernible, with the acceptance ratio ranging from 0% in some cases up to 92% in others.¹⁵

During the interviews, the main reasons for authorising, refusing or withdrawing PA request were assessed. The main reasons mentioned for authorising, were in line with the reported reasons for authorising a request in the annual report of the European Commission¹⁶ and in line with the above mentioned criteria for which PA is required: the healthcare was involved overnight hospital accommodation of the patient in question for at least one night or required use of highly specialised and cost-intensive medical infrastructure or medical equipment.

¹⁴ According to the mobility report twenty Member States, and Iceland, reported that they had implemented a system of prior authorisation and provided data on their use of the system. In contrast to our website analysis, Cyprus has no PA-system in place according to the mobility report.

¹⁵ European Commission (2021) Member State Data on cross-border healthcare following Directive 2011/24/EU Year 2019.

¹⁶ European Commission (2021) Member State Data on cross-border healthcare following Directive 2011/24/EU Year 2019.

The main reasons for refusing PA requests were assessed in the interviews, which were also in line with the main reasons mentioned in the annual report of the European Commission. It appeared that the main reason for refusal is that the healthcare can be provided within a reasonable amount of time in the patient's own MS, taking into account the current state of health and the probable course of the illness of each patient concerned. Another important reason for refusal of PA-requests, may relate to the fact that the healthcare treatment is not included among the national healthcare benefits of the MSs of affiliation.

Other reasons were less commonly used to refuse PA-requests. For example, only two MSs representatives indicated that individual PA-requests were refused, because the experimental treatment requested induced patient-safety risks which could not be regarded as acceptable, while taking into account the potential benefit for the patient of the sought cross-border healthcare. Furthermore, one MSs representative indicated that certain PA-requests may have been refused, because the healthcare provider raised serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety, including provisions on supervision.

Furthermore, it was mentioned during the interviews that the submission of incomplete or missing documents by the patient, may also cause refusals, as well as withdrawals. The main reasons for withdrawal are not included in the annual report of the European Commission¹⁷, but another specific reason for withdrawal of a PA-request that was often mentioned by MS representatives, relates to patients being informed about another way in which healthcare could be provided, including cross-border healthcare that can be provided under the Regulation.

3.1.2 Information provision on prior-authorization to patients

Since the aim of this study is to assess how PA can be streamlined, reduced or simplified, it is not only relevant to assess how and if PA systems are adopted, but also to investigate the way information is provided to patients regarding this topic in terms of 1) comprehensiveness, 2) comprehensibility, and 3) consistency.

It is important to note that the results regarding comprehensiveness and comprehensibility, are primarily based on the results of our website analysis. Subsequently, these results were validated during the interviews and we provided MSs with the opportunity to complement our findings. Since interviews were not (yet) conducted for eight MSs, it should be noted that the results were not validated or complemented for these MSs.

Comprehensiveness

Comprehensive information is needed for patients to make a well-considered decision regarding cross-border healthcare. For that purpose the following specific analytical items (SAIs) were assessed on: 1) whether information that clarifies the difference between the Regulation and Directive and patients' rights under the Regulation is provided and 2) a clear explanation of whether a PA-list as defined by the Directive is in place; 3) the accessibility of the PA-list; 4) level of detail of the PA-list; 5) whether there is information on the PA-procedure; 6) availability of the application form; and 7) whether information on the waiting time for the

¹⁷ European Commission (2021) Member State Data on cross-border healthcare following Directive 2011/24/EU Year 2019.

authorisation to be granted is available on websites. By mapping all this information a clear picture of the comprehensiveness of the information on the PA-lists could be obtained.

Members States and EEA EFTA countries with a PA-system

In total 9 questions were formulated for the 7 separate SAIs (the first SAI consisted of three separate questions). Based on the website analysis, each question was assessed on a 1-4 point scale, with 1 being the lowest and 4 being the highest, adding up to a total amount of 36 points. By dividing the obtained score with the maximum score (36), and multiplying this with 10 a minimum score of 2.5 and maximum score of 10 could be obtained. Note, in case additional information or clarifications were provided during the interviews, this is not included in the scores but mentioned in the paragraph below. In that case, we describe (in general) whether the results of our website analysis were adjusted or complemented for specific items because of new insights gathered during the interviews.

Of those MSs with a PA-system, on average, MSs received 5.7 points out of ten for Comprehensiveness. In total, 11 MSs and one EEA EFTA country scored below 6 points and 11 MSs scored above 6 points.

First, we mapped whether patients have access to information that clarifies the differences between EU Regulation 883/2004 and the Directive 2011/24/EU. 9 MSs provide this information in a general way. Furthermore, it is important for patients that this includes an explanation that in case the conditions laid down in Regulation 883/2004 are met, and unless the patient requests otherwise, the prior authorisation will be granted in accordance with that Regulation, which is generally more favourable for the patient. In total, 5 MSs that have a PA-system in place provided this information on their websites. In addition, 3 MS representatives indicated in the interview that they provide this information to patients when they request this information. However, this information is thus not publicly available on the website.

It is also important that MSs provide either information about patients' rights under the Directive or that MSs assess whether PA could be issued under the Directive when PA is refused under the Regulation. For in total 4 MSs with PA this information was provided on the website. In addition, 15 MS representatives indicated in the interview that patients receive this information once their request under the Directive is refused. However, this information is thus not publicly available on the website.

Patients should have access to a clear explanation of whether a PA-system as defined by the Directive is in place and what the PA-procedure looks like. It was observed that 17 MSs and one EEA EFTA country describe the procedure for PA on their websites. Hence, for 4 MSs and 1 EEA EFTA country the PA procedure was not outlined on the website.

Subsequently, it should be clear for which treatments and/or medical equipment PA is required and thus whether a PA-list is in place. According to our analysis, for those MSs with a PA-system it was clear whether a PA-list is in place in 16 MSs. Hence, four MSs and two EEA EFTA countries with PA do not clearly state on their NCP websites that a PA-list is implemented. Furthermore, in case PA is required for certain treatments, the accessibility of the PA-list was assessed. It was observed that, of those MSs that have a PA-system, in total 15 MSs provide the PA-list on their NCP website. It should be noted however, that as described under the heading "PA-systems", some of these MSs

implemented a PA-list that consists of criteria rather than actual treatments and/or medical equipment.

With regard to the last SAI for comprehensiveness, the availability of a PA-application form, it was found that such an application form was available on the websites of 9 MSs. With regard to information on the processing time relating to PA requests, it was observed that this information was provided on the websites in 12 MSs.

Members States and EEA EFTA countries without a PA-system

For MSs/EEA EFTA countries without a PA-system, four SAIs were assessed with regard to comprehensiveness. Again, each question was assessed on a 1-4 point scale, with 1 being the lowest and 4 being the highest, adding up to a total amount of 16 points. By dividing the obtained score with the maximum score (16), and multiplying this with 10 a minimum score of 2.5 and maximum score of 10 could be obtained. Note, in case additional information or clarifications were provided during the interviews, this is not included in the scores but mentioned in the paragraph below.

Of those MSs without a PA-system, on average, MSs received 4.5 points out of ten for Comprehensiveness. In total, 6 MSs scored below 6 points and one MSs scored above 6 points (SE).

Also for MSs without a PA-system, patients should have access to information that clarifies the differences between EU Regulation 883/2004 and the Directive 2011/24/EU. Three MSs without PA provide this information in a general way. Furthermore, it is important for patient that this includes an explanation that in case the conditions laid down in Regulation 883/2004 are met, the prior authorisation might be granted and costs reimbursed in accordance with that Regulation unless the patient requests otherwise. None of the MSs without a PA-system provided this information on their websites, and only 2 MS representatives indicated in the interview that they provide this information to patients when they request this information. Meaning that this information is not publicly available on the website.

3 MSs without PA stated that they provide information about patients' rights under the Directive when PA is refused under the Regulation or that they assess whether PA could be issued under the Directive.

In case MSs have not implemented a PA-system, it could be helpful for patients to have a clear explanation of whether PA is in place. Four MSs state on their NCP website that PA is not required when seeking healthcare in another MS under the Directive. Furthermore, it should be noted that for 1 MSs and one EEA EFTA country, it was observed that the procedures with regard to reimbursement and pre-approval explained in a very detailed manner on the websites.

Comprehensible

Next to comprehensive information, information provided on PA should be comprehensible for patients. This means that ideally the information should be easily accessible, also for people with disabilities, and available in the native language as well as English language to prevent patients from being excluded. Presenting comprehensible information will mitigate the risk of patients being excluded. The information should be understandable for patients and should not discriminate between patients, for example from different socioeconomic backgrounds or due to language barriers. Therefore, the Mapping Tool

included SAIs on 1) language; 2) available options for people with decreased sensory functioning (visual and hearing); 3) whether information on PA is easy to find (e.g., whether there is a separate header/section for PA at the website); 4) whether information (general information; the PA-list; PA-procedure) is provided in laymen terms; 5) availability of contact details; and 6) frequently asked questions (FAQs) on PA. Gathering this information provided an overview of the comprehensiveness of the information on PA.

Members States and EEA EFTA countries with a PA-system

For comprehensibility, there were 8 questions included covering 8 SAIs. In total 9 questions were formulated for the 7 separate SAIs (the first SAI consisted of three separate questions). Based on the website analysis, each question was assessed on a 1-4 point scale, with 1 being the lowest and 4 being the highest, adding up to a total amount of 32 points. By dividing the obtained score with the maximum score (32), and multiplying this with 10 a minimum score of 2.5 and maximum score of 10 could be obtained. Note, in case additional information or clarifications were provided during the interviews, this is not included in the scores but mentioned in the paragraph below.

Of those 22 MSs with a PA-system, on average 7.1 points out of 10 in total were received for comprehensibility. Four MSs received less than six points, but none of these MSs scored below 5 points.¹⁸

With regard to language, 17 MSs and one EEA EFTA country with PA provided information in English in addition to the native language(s). For 7 of these MSs, all information was completely provided in English, for 10 it was partly provided in English. On 2 of these 25 websites, the information was also provided in a third language. 4 MSs provided the information only in the native language.

It was also assessed whether there are options available for people with decreased sensory functioning (visual/hearing). 7 MSs and 1 EEA EFTA country with PA had such options available, of which most had the option to increase the text size. Two MS had an option to read the information out loud.

Furthermore, it was analysed whether general information on PA was easy to find. For most MSs it was determined that the information was easy to find, for example because a separate header or section for PA was available on the website. For 5 MSs and 1 EEA EFTA country, the information was considered as moderately easy to find and for 2 MSs and 1 EEA EFTA country it was received as difficult to find.

It was assessed whether the general information on PA was provided in laymen terms. Of those MSs with a PA-system, it was observed that 2 MSs provided only very complex information and not in laymen terms at all. Eight MSs and one EEA EFTA country with PA scored moderately on this item. For 9 MSs with PA, the information was perceived as easy to understand.

Also, the PA-list itself was assessed on complexity in terms of language use (in addition to the content of the PA-list described above). For 12 MSs the PA-list itself was defined as easy to understand, for one MSs the PA-list was perceived as moderately easy to understand, and for 6 MSs this was perceived as difficult to understand. Furthermore, it should be noted, that as described under the heading "PA-systems", 5 MSs and one

¹⁸ Note, the number listed under this heading do not always add up to 22 due to unavailability of information or a PA-list.

EEA EFTA country implemented a PA-list that consists of criteria rather than actual treatments and/or medical equipment.

According to our analysis, the PA-procedure was provided in laymen terms for 9 MSs that have implemented PA, for nine MSs and one EEA EFTA country this was perceived as moderately easy to understand, for 2 MSs this was perceived as not easy to understand.

Lastly, in case patients seek more information, it is important that contact details are provided on the website. Most MSs with a PA system (15) and 1 EEA EFTA country provided both an email address and phone number. Five MSs and 1 EEA EFTA country provided either an email address or a phone number.

An overview of frequently asked questions could also help patients in finding information easily. It was observed that 8 MSs with a PA-system do so.

Members States and EEA EFTA countries without a PA-system

- For MSs not having a PA system, only 6 questions were assessed covering 6 SAIs for comprehensibility. Again, each question was assessed on a 1-4 point scale, with 1 being the lowest and 4 being the highest, adding up to a total amount of 24 points. By dividing the obtained score with the maximum score (24), and multiplying this with 10 a minimum score of 2.5 and maximum score of 10 could be obtained. Note, in case additional information or clarifications were provided during the interviews, this is not included in the scores but mentioned in the paragraph.

On average, MSs received 7.2 points out of 10 in total. None of the MSs and one EEA EFTA country received less than six points.

With regard to language, all MSs and EEA EFTA countries without PA, provided information in English in addition to the native language(s). For 4 of these MSs, all information was completely provided in English, for 3 and 1 EEA EFTA country it was partly provided in English. On three of these websites, the information was also provided in a third language.

It was also assessed whether there are options available for people with decreased sensory functioning. Five MSs without PA had such options available, of which most had the option to increase the text size. One MS without PA had an option to read the information out loud and two MSs had an option for sign language.

We also determined whether information on PA was easy to find for those MSs that do not have a PA-system. Four MSs and 1 EEA EFTA country provided easy access to information on PA, 1 MS scored moderately and 1 was scored as not easy to find.

Two MSs without a PA-system provided information on PA that was easy to understand, 3 MSs were perceived as moderately clear, 3 MSs/EEA EFTA countries were assessed as providing unclear information.

Lastly, in case patients seek more information, it is important that contact details are provided on the website. Most MSs without a PA system (4) provided both an email address and phone number. Two MSs and 1 EEA EFTA country provided either an email address or a phone number. One MS provided only a contact form.

An overview of frequently asked questions could also help patients in finding information easily. It was observed that 4 MSs without a PA-system do so.

Consistency

The Evaluative Study of the Directive (2015),¹⁹ showed that there are in some cases disparities between information provided between NCPs and health insurance providers. Information of the NCP should be in line with information of other parties, such as health insurers, healthcare providers and patient organisations. For both MSs with a PA-system in place and MSs without such a system, it is important that the information on PA is consistent. Against this background, it was mapped, via bilateral contact with MSs, whether there is any coordination on information regarding PA between NCPs and patient organisations, health insurance providers/payers and healthcare providers.

The extent to which coordination and communication with regard to the Directive takes place, generally depends on how the different organisations are structured within MSs. For example, in some MSs NCPs are intertwined with health insurers, but in other MSs, NCPs are organised outside the system and they may function as the 'watchdog' for health insurers and healthcare providers. Evidently, closer communication and coordination exists in those MSs where organisations are intertwined.

With regard to information on the PA-procedure and content of the PA-list, it was observed that in most MSs that have implemented PA, there is little to no coordination and communication between NCPs and other stakeholders on this specific topic. In some MSs, patient organisations were involved at time of the implementation of the Directive, but in general coordination and communication now only concerns individual cases and PA-requests. In some MSs, PA-requests are dealt with on a local level, with a strong focus on providing streamlined information.

Despite little or no communication and coordination on the Directive and/or PA, most MS representatives indicated that they are not aware of any inconsistencies. Only one MS indicated that they are aware of the fact that healthcare insurers ask patients to pay for certain information. This information however, is freely accessible and provided in a more complete version by the NCP. One MS indicated that they are aware of private individuals who set themselves up as a third party that can help patients with the PA application. However, they do not always follow the procedure and sometimes give inaccurate information. In addition, this MS indicated that hospitals abroad can engage in spreading false and misleading information to patients and that the accuracy of documentation from hospitals abroad can be doubted.

3.2 What are the underlying reasons for the different prior-authorisation approaches?

A PA-system should be adopted based on overriding reasons of general interest, such as planning requirements, or the wish to control costs. These reasons may differ between and even within MSs. In the following paragraphs we elaborate on the different reasons that MSs mentioned for (not) having adopted a PA-system. The information with regard to the underlying reasons was obtained through the interviews. For those

¹⁹ Evaluative study on the cross-border healthcare Directive (2011/24/EU), 2015. Available at: http://ec.europa.eu/health/sites/health/files/cross_border_care/docs/2015_evaluative_study_frep_en.pdf.

MSs for which interviews are not (yet) conducted, the underlying reasons for having a certain PA-system remain yet unclear.

3.2.1 The underlying reasons for having a prior-authorization system

For those MSs that have implemented a PA-list, it became apparent from our analysis that in general there are two main reasons mentioned for having introduced the system: 1) protection of the healthcare system; 2) providing patients with the certainty of insurance coverage; 3) alignment with national healthcare system.

Protection of the healthcare system

Under the Directive, patients are free to seek healthcare in another MS. If they would do so in great numbers, this may lead to underutilisation of equipment or services in the MS of affiliation. Given the large amount of the healthcare budget being spent on medical equipment, this, in turn, could lead to a disproportionate burden on MSs social security budgets.²⁰ This is one of the most important reason why MSs are, under the Directive, allowed to subject the reimbursement of certain healthcare treatments to PA.

Of those MSs that have PA-list in place and participated in the interviews, most MSs indicated the protection of their healthcare system is the main reason for the implementation of a PA-system.

Some MSs explained that it was a political decision to introduce the PA-system. At the time the Directive was implemented, the effect on MSs' healthcare systems was uncertain and for some MSs, the introduction of a PA-system was a means to monitor the effect of the Directive on their own healthcare systems.

Although MSs are allowed to subject reimbursement to PA in order to protect their own healthcare system, MSs are only allowed to do so for inpatient care or for outpatient care that is cost intensive or highly specialised. Hence, almost all MSs with a PA-list included inpatient treatment and examinations as a separate category with at least one overnight stay and in case treatments and/or medical equipment are included on the PA-list, these are listed under 'outpatient care'. In some cases it is not explicitly mentioned whether the treatments and/or medical equipment listed concern outpatient or inpatient care. In that case it is assumed that it refers to both inpatient and outpatient care. As described under the heading 'Implementation of the PA-system', the PA-lists differ significantly in the extent to which the treatments and/or medical equipment are further specified and the number of treatments and/or medical equipment that are included on the list ranges from 6 to 180 separate items. Subsequently, the treatment and/or medical equipment mentioned differ subsequently. The table below provides an overview of treatment and medical equipment that are included on the PA-list of at least two MSs.

Treatment/Medical equipment	Number of MSs that included treatment in PA-list
CT-scanner (Computer Tomography)	12
PET-scanner	10
MRI (Magnetic Resonance Imaging)	7
Hyperbaric chamber	6
Radiotherapy	6

²⁰ <http://curia.europa.eu/juris/liste.jsf?language=en&num=C-512/08>.

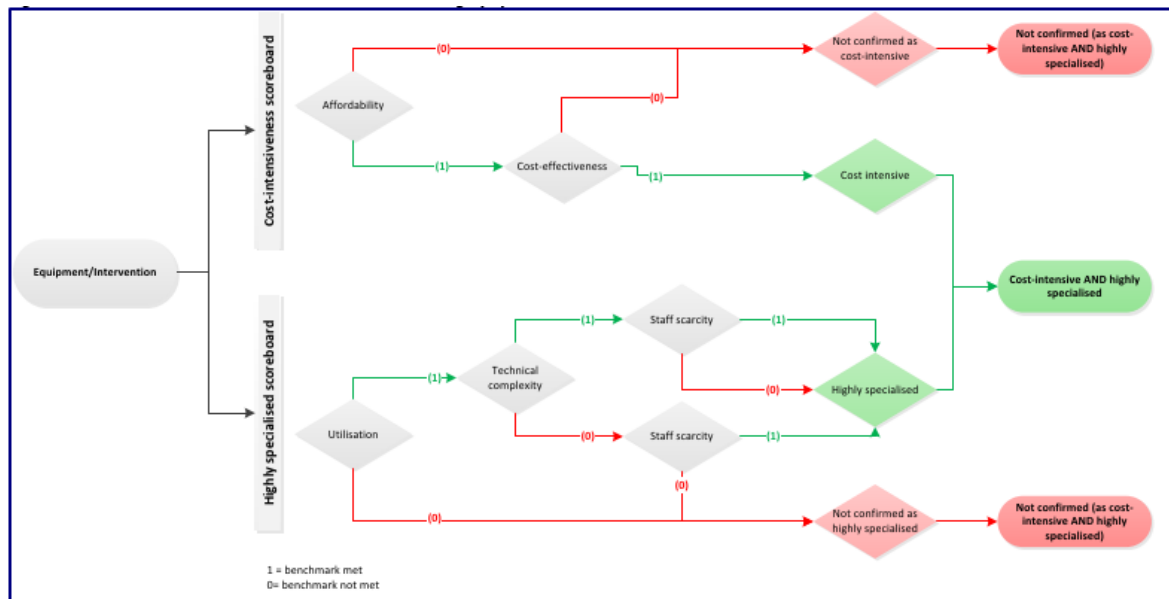
*Study on Enhancing implementation of the Cross-Border Healthcare Directive
2011/24/EU to ensure patient rights in the EU
Mapping and Analysis of Prior-authorisation lists: analytical report*

Treatment/Medical equipment	Number of MSs that included treatment in PA-list
Human genetic examinations	5
IVF	4
Cancer treatment	3
Clinical and biological care of medically assisted procreation and biological activities of prenatal diagnosis.	3
Placement or replacement of defibrillators / pacemakers	3
Stereotactic Radio Surgery	3
Dialysis	2
Radioisotope diagnostics	2
Endoscopies	2
Angiography	2
Coronagraphy	2
Gamma knife	2
Scintillation camera/emission tomography/positron camera	2
Nuclear magnetic resonance imaging device for clinical use (included in addition to MRI)	2
Nuclear medicine	2
Extracorporeal lithotripsy equipment	2
Treatments of disabilities which require the following for their correction or improvement	2
Pharmacological treatments or treatments with biological products whose monthly cost exceeds €1500	2

The question is whether the included treatments and/or medical equipment are indeed cost-intensive *and* highly specialised. For that purpose, the 'Combined decision-tree for cost-intensive and highly specialised scoreboards', was developed in the previously conducted literature-based approach to define the concept of healthcare which requires "highly specialised and cost-intensive medical infrastructure or medical equipment"²¹. The decision tree is showed in the figure below.

²¹ <https://op.europa.eu/en/publication-detail/-/publication/edb699ad-32c9-471e-b61a-a309cc4b2517/language-en>.

Figure 3.1 Combined decision-tree for cost-intensive and highly specialised scoreboards



We aimed to apply the decision tree for the five most commonly included treatment and medical equipment, i.e., CT-scanner, PET-scanner, MRI, hyperbaric chamber and radiotherapy. For the latter however, the equipment costs were not included on the French list of equipment (discussed in case C-512/08 (Commission v. France) and hence not included in the literature study. Therefore, we assessed the cost-intensiveness and highly specialised criteria for the first four medical equipment.

With regard to affordability two benchmarks are formulated in the literature-based approach:

- The Average Life Time Equipment Costs (ALEC) of the equipment involved in the intervention is less than 333 times the Health Expenditure per capita (PPP);
- The MLEC of the equipment involved in the intervention is less than 6 times the HE per capita (PPP).

Except for Liechtenstein, PET, MRI and medical scanners (including CT-scanners) do not meet the first affordable benchmark. Two MSs and one EEA EFTA country do not meet the MLEC benchmark for Medical Scanners, however these MSs/EEA EFTA countries have no PA-list or have not included a medical scanner on the list. Hence, for those MSs that included PET, MRI and/or medical scanners (including CT-scanners) on their PA-list, these are confirmed by the literature review as being cost-intensive.

For 5 MSs and 2 EEA EFTA countries hyperbaric chambers are considered as affordable. Of these MSs, one MSs included the use of hyperbaric chamber on the list. For the remaining 5 MSs that included the use of a hyperbaric chamber on their PA-list, this is confirmed as being cost-intensive.

When the affordability benchmark is met, it is relevant to assess cost-effectiveness. A piece of equipment meets the cost-effectiveness benchmark when, the share of average equipment costs (ALEC per activity) is at least 2.92% of the intervention costs (mean IC). This is only the case for medical scanners when the minimum costs are considered (including ultrasonic and abdominal scanning systems). Computer Tomography (CT) is considered in the maximum cost price for medical scanners and hence, similar to the

other medical equipment (PET, MRI, and hyperbaric chamber), considered to be cost-intensive.

With regard to highly specialised, a combination of the following three benchmarks were proposed in the literature-based approach in order to determine whether an intervention can be considered as highly specialised, including 1) utilisation, 2) technical complexity, and 3) staff. With regard to availability and utilisation the benchmark was determined as follows: the number of activities per year per 1,000 population should at most 60.2. PET and MRI meet this benchmark and meet the utilisation indicator. For the other medical equipment this remained unclear.

With regard to technical complexity, the indicator for technical complexity of the device involved in an intervention-indication combination should be at least 0.79%. PET, MRI, medical scanners, and hyperbaric chamber meet this and are thus considered as being complex.

Lastly, the indicator for staff scarcity is at most 11.41, i.e. there are at most 11.41 physicians with the relevant medical specialty per 100,000 population (staff). For the application of the hyperbaric chamber it was not possible to determine this. PET, MRI and medical scanners however, meet this indicator according to the French list.

In conclusion, according to the French list of equipment the most commonly included medical equipment on the PA-lists, i.e., CT-scanner, PET-scanner, MRI, hyperbaric chamber, seems to meet the criteria of cost-intensive and, if it could be assessed, the highly specialised healthcare. However, it is important to note that for the French list data were collected for the year 2010 and the benchmark is developed for France. Hence, there is need for a more up-to-date benchmark to assess the cost-intensive and highly specialised criteria.

Providing patients with the certainty of insurance coverage

From previous studies, it became apparent that sufficient information provision on cross-border healthcare under the Directive in general remains a challenge.²² This includes communication on the inter-linkages between the Directive and Social Security Regulation, information on patient's rights, and reimbursement of cross-border healthcare costs. For one MSs, complexity of the system, in particular with regard to reimbursement, is the reason for introducing a PA-system. In that way, all steps can be checked beforehand to make sure that patients receive their reimbursement. It should be noted however, that an important aim of the Directive is less red-tape for patients and that under the Directive seeking PA should be the exception rather than the rule.²³ Notably, it was mentioned by two MSs without PA²⁴ that they have a prior notification system in place as described under art. 9(5) of the Directive 2011/24/EU, encouraging patients to seek pre-approval to ensure that they receive reimbursement without undue delay before going abroad.

²² Study on cross-border health services: enhancing information provision to patients (2018). https://ec.europa.eu/health/sites/health/files/cross_border_care/docs/2018_cross-border_frep_en.pdf.

²³ https://ec.europa.eu/commission/presscorner/detail/en/MEMO_13_918.

²⁴ Note, during these two interviews the application of a prior-notification system was mentioned. It was not systematically assessed for all MSs/EEA EFTA countries whether a prior-notification system as defined under art. 9(5) of the Directive 2011/24/EU is in place.

Alignment with own healthcare system

During interviews with representatives from the MSs it became apparent that for 2 MSs the choice was made to implement the PA-system in order for the Directive to align with their own healthcare system and the Social Security Regulation. In that way the procedures are clear and simple for patients, while also being in line with the procedures that are already in place in the MSs.

3.2.2 The underlying reasons for not having a PA-system

Eight MSs/EEA EFTA countries do not have a PA-system in place. The main reasons for not having implemented or removed of the PA-system is related to a lack of need for such a system. This reason for this lack of need was mainly related to a (expected) limited number of PA-requests, which is the case for 3 MSs and one EEA EFTA country, or a lack of financial threat to the healthcare system in 2 MSs. For example in one MS, only one request was received at time PA was implemented, which, in turn, is related to the limited number of patients seeking care abroad. For 1 MS that does not have a PA-system, it appeared that PA is still requested by the healthcare insurer or that a variation of PA is implemented. For two MSs it remained unclear why it was decided to not opt for such a system.

4 Further steps

In light of our study to enhance the implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU we mapped:

1. How Prior-authorisation is applied in the Member States and EEA EFTA countries;
2. What the underlying reasons are for the different Prior-authorisation approaches in the Member States and EEA EFTA countries?

The results of the current mapping exercise, build on the website analysis that was conducted in light of the 2018 study to enhance information provision to patients in the context of cross-border healthcare.²⁵ This website analysis was broad and focussed on several elements of NCP websites, also including SAIs to assess information related to patients' rights and the differences between the Directive 2011/24/EU and Regulation 883/2004. It was observed that less than half of the websites included information on this difference and in-depth information on patients' rights was generally lacking. In line with these observations, in our current mapping exercise we still observed that only 11 MSs explain the difference between the Regulation and Directive and 5 MSs provide information on their websites explaining that in case the conditions laid down in the Regulation 883/2004 are met, PA is requested under the Regulation and often more beneficial to the patients. During the workshop that was conducted in light of the current mapping exercise, information provision with regard to patients' rights and the difference between the Directive and Regulation was also discussed. Several MSs explained and agreed that the difficulty lies in striking the right balance between accuracy (including legal aspects) and user friendliness of information (simple versus complete).

With regard to prior-authorisation, the 2018 study assessed whether PA-lists are available and information on the time period to process a PA-request is provided on NCP websites. With regard to the latter, MSs scored poorly. Though there might be some improvement, to date still less than half of the MSs provide information on the processing time related to PA requests. The availability with regard to PA-lists has hardly improved: of the 20 MSs and 1 EEA EFTA country that have implemented PA, 14 MSs have an exhaustive PA-list available to date (compared to 13 MSs in 2018). Besides, the current mapping exercise showed that the content of PA-lists differs significantly, with very general and broad PA-lists on the one hand and extensive lists of up to 180 separate items on the other hand.

The current mapping exercise showed that there is still room for improvement with regard to information provision on prior-authorisation under the Directive. The next step of our study is therefore, to develop Guiding Principles for streamlining and simplifying prior-authorisation lists to make them more accessible, more transparent and understandable to patients. These Guiding Principles will in any case address the following aspects:

- clear information on which treatment and/or medical equipment require prior- authorisation and which do not;
- accessibility and comprehensibility of information on PA (e.g., that information should be available in the native language as well as English);
- PA-procedures and (reduction of) administrative burden;
- making reference to helpful tools on PA mentioned in the Toolbox for Cross-border Healthcare.

²⁵ Study on cross-border health services: enhancing information provision to patients, 2018.

Annex A Legal Context²⁶

Directive 2011/24/EU

In March 2011, the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (hereafter the Directive) was adopted.²⁷ The Directive clarifies the rights of patients to seek reimbursement for healthcare received in another Member State (MS) and ensures that these rights can be used in practice. It provides a framework for cross-border healthcare and 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.*"²⁸

The Directive clarifies the rights of patients to seek reimbursement for healthcare received in another Member State (MS).²⁹ Decisions about the healthcare basket to which citizens are entitled, as well as the mechanisms used to finance and deliver that healthcare, must be made at the national level.³⁰

Social Security Regulations

Before Directive 2011/24/EU entered into force, Regulation (EC) No. 883/2004 on the coordination of social security systems already regulated the reimbursement of healthcare costs that might become necessary during a temporary stay in another MS (if the conditions of Regulation (EC) No. 883/2004 are met). The Social Security Regulations aim to coordinate social security systems and to ensure the protection of EU/EEA or Swiss citizens when moving and travelling to another MS. The general principle under the Regulations is that patients have the right to access health services abroad and to enjoy assumption of costs as though he or she was insured under the social security system of that country and thus equally as domestic publicly insured patients.

The Regulations set out rules to determine the applicable social security legislation to which an insured person is subject. As a general rule of thumb, citizens are only subject to the social security legislation of one country at a time. In most cases, this will be the social security legislation of the country of residence. However, in a number of cases the patient will be entitled to healthcare in his/her country of residence while insured under the social security legislation of another country, i.e. the competent MS. The latter will, for example, be the case for posted workers and frontier workers. In addition, the Regulations envisage a broad range of possibilities for accessing healthcare outside the patient's home country:

- Medically necessary treatment under the European Health Insurance Card during a short-term stay abroad, such as holiday, business trip, family visit. (also referred to as unplanned treatment);

²⁶ This information is cited from: Study on cross-border health services: enhancing information provision to patients (2018). https://ec.europa.eu/health/sites/health/files/cross_border_care/docs/2018_cross-border_frep_en.pdf.

²⁷ 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.

²⁸ Directive 2011/24/EU, recital 10.

²⁹ Commission Report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, 4 September 2015, COM(2015) 421 final, p. 2.

³⁰ Directive 2011/24/EU, recital 5.

- Seeking healthcare abroad with the prior authorisation (S2 form) from the patient's national health service/ health insurance provider (also referred to as planned treatment);
- Special permanent arrangement for posted workers, frontier workers and pensioners residing outside the country of social security insurance.

Directive 2011/24/EU versus Social Security Regulations

Any patient who requests an authorisation to receive treatment (appropriate for their condition) in another MS, should be granted this authorisation under the conditions provided for in the Regulations, if the conditions of the Regulations are met. This is the case when the treatment in question is among the benefits provided for by the legislation in the MS where the patient resides, and when the patient cannot be given such treatment within a time limit that is medically justifiable, taking account of their 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 the Directive, the benefits, which apply to reimbursement, should be limited to those, which apply under the Directive.

Where the patient is entitled to cross-border healthcare under both the Directive and Regulation (EC) No. 883/2004, and the application of the Regulation is more advantageous to the patient, the patient's attention should be drawn to this by the MS of affiliation. In some cases, patients have more beneficial rights under the Regulation. This is because the Regulation provides that reimbursement of costs will be done according to the legislation obtained in the MS of treatment, instead of according to the legislation of the MS of affiliation. Moreover, the Regulation may lead to a situation whereby the insured person does not have to pay the medical costs upfront.³¹ It is important to note that the Directive does not have an effect on insured person's rights under the Social Security Regulations. Consequently, the Directive does not deprive patients of the more beneficial rights guaranteed by the Regulation on the coordination of social security systems when the conditions are met.³²

Prior authorisation under the Social Security Regulations

Under the Social Security Regulations, planned medical treatment in another MS is only possible under the condition of prior authorisation (S2 form) granted in advance by the competent institution of the MS under whose social security legislation the patient is insured. An exception can be made for family members with residence in another MS than the insured person³³ or pensioners and their family members with residence in another MS,³⁴ if this MS of residence has opted for reimbursement on the basis of a fixed amount.³⁵ ³⁶ In this case, the MS of residence shall be competent for the authorisation (i.e. the authorising institution). The prior authorisation cannot be refused in case two cumulative conditions are met:

³¹ Directive 2011/24/EU, recital 46.

³² Directive 2011/24/EU, recital 31.

³³ For family members of an insured person residing in another MS, which has opted for a system of reimbursement between public health systems on the basis of fixed amounts instead of actual expenditures, the insurance institution of the place of residence will be competent to grant authorisation: art. 20(4) Regulation (EC) 883/2004.

³⁴ A same exception is made for pensioners and their family members, who continue to be covered under the social security scheme of a previous MS, but who now reside in another MS which has opted for reimbursement based on fixed amounts: art. 27(5) Regulation (EC) 883/2004.

³⁵ Annex III of Regulation (EC) No. 987/2009, consolidated version of 11 April 2017 (last consulted on 19 April 2018).

³⁶ Art. 20(4) Regulation (EC) 883/2004.

- The treatment for which prior authorisation is asked, is included in the basket of services of the institution of the place of residence; and
- The treatment cannot be provided in the MS of affiliation within a medically justifiable time limit, taking into account the current state of health of the patient and the probable evolution of his/her condition.³⁷

To obtain prior authorisation, the treatment must be included in the basket of services covered under the social security scheme of the MS of treatment. Besides, the competent institution is not obliged to grant authorisation in case the treatment is not included in its own basket of services. In this case, patients may file a request for authorisation, however, the competent institution will decide at its sole discretion whether or not authorisation will be granted. It can therefore be concluded that in order to obtain authorisation, the treatment in most cases will have to be included both in the basket of services of the MS of treatment and of the competent MS. Similar as for unplanned care under the Social Security Regulations, private care is (normally) not covered.

Prior authorisation under the Directive

Under Directive 2011/24/EU, the general rule is that no authorisation is required. However, MSs may opt for a system of prior authorisation. In this case, the requirement of prior authorisation will only be possible in case of:

- Healthcare which is subject to planning requirements and which involves an overnight hospital stay or highly specialised and cost-intensive medical infrastructure and equipment;
- Safety-risk for the patient or the public population;
- Treatment provided by a healthcare provider that could give rise to serious and specific concerns relating to quality or safety.³⁸

Any system of prior authorisation must be necessary and proportionate to the objective to be achieved and may in no case constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of persons.³⁹ MSs are obliged to make publicly available which health services are subject to prior authorisation.⁴⁰ Many MSs have opted for a system of prior authorisation under Directive 2011/24/EU.

Authorisation may not be refused in case the patient is entitled to the treatment in the MS of affiliation and cannot receive the treatment concerned on the own territory of the MS within a time limit that is medically justifiable, taking into account the patient's specific current, future or past health situation, the degree of the patient's pain and the nature of the patient's disability.⁴¹ In addition, the grounds of refusal are limited as well:

- Patient-safety risk;
- Safety-risk for the general public;
- Treatment that is considered not to be in accordance with standards and guidelines of quality care and patient safety;
- If the benefits in kind concerned can be provided on the own territory within a medically justifiable time limit, taking into account the current state of health and the probable course of the illness of the patient concerned.⁴²

³⁷ Art. 20(2) Regulation (EC) 883/2004.

³⁸ Art. 9 Directive 2011/24/EU.

³⁹ Art. 8 (1) Directive 2011/24/EU.

⁴⁰ Art. 8 (7) Directive 2011/24/EU.

⁴¹ Art. 9(5) Directive 2011/24/EU.

⁴² Art. 9(6) Directive 2011/24/EU.

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Annex B Desk study

Member State	General website	Link used for information on PA
Austria	https://www.gesundheit.gv.at/service/patientenmobilitaet/kontaktstelle-patientenmobilitaet	https://www.gesundheit.gv.at/service/patientenmobilitaet/versicherungsmitgliedstaat/vorabgenehmigung
Belgium	www.cross-borderhealthcare.be	https://www.health.belgium.be/nl/voor-welke-geneeskundige-zorg-moet-uit-een-voorafgaande-toestemming-aanvragen
Bulgaria	www.nhif.bg	https://www.nhif.bg/page/62
Croatia	www.hzzo.hr	http://www.hzzo.hr/en/national-contact-point-ncp/using-healthcare-another-member-state-eueeeaswitzerland/planned-3
Cyprus	www.moh.gov.cy/cbh	https://www.moh.gov.cy/moh/cbh/cbh.nsf/page15_en/page15_en?OpenDocument
Czech Republic	www.kancelarzp.cz	https://www.kancelarzp.cz/cs/pojistenci/prava-naroky-eu/narok-kategorie/cesta-za-zdrav-peci
Denmark	http://stps.dk/da/borgere/internationalisygesikring/nationalkontaktunktforbehandling-i-eueoes	https://en.stps.dk/en/citizens/national-contact-point-for-cross-border-in-the-eueea/reimbursement-of-healthcare-purchased-abroad/
Estonia	www.haigekassa.ee/kontaktpunkt	https://www.haigekassa.ee/en/kontaktpunkt/planned-medical-treatment-abroad
Finland	www.eu-healthcare.fi	https://www.eu-healthcare.fi/health-services-abroad/i-want-to-go-abroad-for-treatment/seeking-treatment-abroad-with-a-prior-authorisation/
France	http://www.cleiss.fr/presentation/pcn.html	https://www.cleiss.fr/particuliers/partir/soins/ue/soins-programmes-ue-eee_en.html#autorisation
Germany	www.eu-patienten.de	https://www.eu-patienten.de/en/behandlung_ausland/geplante_behandlung_1/kostentraeger_eu/kostentraeger_eu_2.jsp
Greece	https://eu-healthcare.eopyy.gov.gr/gr/home.aspx	https://eu-healthcare.eopyy.gov.gr/en/3_1.aspx
Hungary	http://www.patientsrights.hu/	http://www.eubetegjog.hu/elozetes-engedelyezesi-kotelezettseg-alattartozo-ellatasok.html
Ireland	http://hse.ie/eng/services/list/1/schemes/cbd/CBD.html	https://www2.hse.ie/services/cross-border-directive/before-you-go-abroad.html
Italy	http://www.salute.gov.it/portale/temi/p2_4.jsp?lingua=english&area=healthcareUE	http://www.salute.gov.it/portale/cureUE/dettaglioContenutiCureUE.jsp?lingua=english&id=3812&area=cureUnioneEuropea&menu=vuoto
Latvia	www.vmnvd.gov.lv	http://www.vmnvd.gov.lv/en/cross-border-healthcare-contact-point/provision-of-services-in-the-eu
Lithuania	https://www.ncp.lt/	https://www.ncp.lt/?p=71&lng=en
Luxembourg	www.mediateursante.lu	https://cns.public.lu/en/assuree/vie-privee/a-etranger/traitement-etranger/pays-membre-ue-eee-suisse.html

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Member State	General website	Link used for information on PA	
Malta	http://health.gov.mt/en/cbhc/Pages/Cross-Border.aspx	https://deputyprimeminister.gov.mt/en/cbhc/Pages/Cross-Border.aspx	
The Netherlands	www.cbhc.nl	https://cbhc.hetcak.nl/nl/meer-over-behandelings-in-eeu-land	
Poland	http://www.kpk.nfz.gov.pl/en/	http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/leczenie-planowane-uprzednia-zgoda-na-uzyskanie-leczenia-poz-granicami-kraju.html#informacje-dla-pacjenta	
Portugal	http://diretiva.min-saude.pt/	https://diretiva.min-saude.pt/autorizacao-previa/	
Romania	www.cnas-pnc.ro	www.cnas-pnc.ro	
Slovakia	www.udzs-sk.sk	http://www.udzs-sk.sk/postupy-pre-jednotlive-kategorie-osob	
Slovenia	http://www.nktz.si/wps/portal/nktz/home	http://www.nktz.si/wps/portal/nktz/home/abroad/planned!/ut/p/z1/rc5BT8JQDMDxr_I87EhacFE4DgIDFDXGkPEuprAyHoy-sRUKfno3PMAH4Njml_YPFhKwQieXkTovInfwj59h-3hJH58x0m3N0KMcD7-Gn30OthvwxTsLcC3zxrELzh_HYYYP4fnhU45G8wysAXppuVk7SHJvJOMIqWnFJiiJxFOzZ5Tt6LcaMmkexY1_8KkRzbqDZ83dKy0llfhi6a0Mk5MlfsTi6PmpdseDjYCu_KiffZIZKet3wB_eHIZiQZ40xDgvRuKnV10q-jhD4HTOos!/	
Spain	https://www.mscbs.gob.es/pnc/home.htm	https://www.mscbs.gob.es/en/pnc/ciudadanoEsp/infAutorizPrevia.htm	
Sweden	www.forsakringskassan.se	https://www.forsakringskassan.se/privatpers/resa_arbeta_studera_eller_fa_vard_utomlands/planerad_vard_utomlands	
EEA country	EFTA	General website	Link used for information on PA
Iceland		http://www.sjukra.is/english	https://www.sjukra.is/english/health-insurance-abroad/medical-treatment-abroad/
Lichtenstein		https://www.llv.li/inhalt/117352/amtsstellen/nationale-kontaktstellen	https://www.llv.li/inhalt/117352/amtsstellen/nationale-kontaktstellen
Norway		https://helsenorge.no/norwegian-national-contact-point-for-healthcare1	https://www.helsenorge.no/en/treatment-abroad/hospital-treatment-and-other-specialist-health-services-in-eea-countries/

Annex C Interview guideline

Name	
Organisation/association	
Date	
Interviewer	

Background and explanation

Commissioned by the European Commission, Directorate-General for Health and Food Safety (DG SANTE), ECORYS Nederland B.V., Technopolis and Spark Legal Network are conducting a study *to enhance the implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU*.

Many Member States have implemented a prior-authorisation system under the Directive 2011/24/EU. One of the aims of the study is to develop Guiding Principles that will serve as a recommendation for streamlining and simplifying prior-authorisation (PA). For that purpose, we are currently mapping and analysing if and how PA is applied across Member States and what information is provided on Member States' websites on this topic.

The aim of the current interview is to validate and complement the results of our website analysis. Kindly note that this interview guide includes general questions that will provide guidance during the interview, which we will specify during the interview where relevant. Besides, we do not expect you to have an answer to all questions and it is also possible and appreciated to share additional information or relevant sources by email subsequent to the interview.

We would like to thank you for your time for participating in this interview. Any information you will provide will be treated **confidentially** and we will not quote anything without your permission.

I. Characteristics of the PA-system

1. Is there a PA-list as defined by the directive in place?
2. Why are the underlying reasons for having this/no PA-system? Do you think that these underlying reasons still apply?
3. What is included on the PA-list?
 - a. Is it possible to share the PA-list with us? (if applicable)
 - b. Does the PA-list include medical treatments which require hospital accommodation of the patient in question for at least one night (in the MS of affiliation or in the MS of treatment?)
 - c. Does the PA-list include all the healthcare subjects to PA referred to in Article 8 (2) of Directive 2011/24/EU? (a) involves overnight stay or 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
4. Does information exist on why certain treatments/medical equipment are included on the PA-list?
5. Which criteria are used to assess whether PA is (if applicable):
 - a. Under which criteria is PA required? (if applicable)

- b. Under which criteria should PA be issued for treatments/medical equipment that are on the PA-list? (if applicable)
- c. Under which criteria should PA be refused for treatments/medical equipment that are on the PA-list? (if applicable)
- 6. What is the procedure for requesting PA and what is the time period for PA-requests to be dealt with? (if applicable)
- 7. Is there a procedure in place for issuing, in individual cases, the authorisation retroactively/granting reimbursement even if prior authorisation was not issued? (if applicable)

II. Information provided to patients

- 8. Can patients find information on the NCP website on whether a PA-list as defined by the directive is in place?
 - a. Do you think information on PA is clear and easy accessible for patients?
- 9. If PA is required, can patients find information on the PA-procedure in place on the NCP website?
 - a. Do you think information on the PA-procedure is clear and easy accessible for patients?
 - b. Is there an application form available on the NCP website and information on the time period for requests to be dealt with? (if applicable)
- 10. Is the PA-lists accessible from the NCP website and easy to find for patients? (if applicable)
 - a. Is the PA-list (i.e., the treatments/medical equipment) that is available to patients described in categories or in detail?
 - b. Is information provided to patients on why certain treatments/medical equipment are included on the PA-list? Does this information exist in general (in case not provided to patients)?
 - c. Do you think that the PA-list itself is easy to understand for patients?
- 11. Is information available that clarifies the differences between EU Regulation 883/2004 and the EU Directive 2011/24, explaining that:
 - a. in case the conditions laid down in Regulation 883/2004 are met, the prior authorisation will be granted in accordance with that Regulation unless the patient requests otherwise?
 - b. Patients' rights under the Directive in case PA under the Regulation will be refused?
 - c. When the competent authority refuses PA under the Regulation, does it assess whether PA could be issued under the Directive?

III. Coordination on the PA-list

- 12. Is there coordination between the NCP and patient organisations on PA-lists?
- 13. Is there coordination between the NCP and health insurance providers/payers on PA-lists?
- 14. Is there coordination between the NCP and health care providers on PA-lists?
- 15. Are there any signals that there inconsistencies exist in (information provision on) PA?

IV. Operationalisation of the PA-system (if applicable)

- 16. Do you know the number of requests (approximately) for PA (on a yearly basis):
 - a. Received;
 - b. Refused;
 - c. Accepted;
 - d. Withdrawn?
- 17. What are the main reasons for the refusal of PA?

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18. Is information available on patient complaints on PA-lists in place? If yes, do you know what the main complaints are? (categories) (if applicable)
19. Is information available on patient complaints on PA-procedure in place? If yes, do you know what the main complaints are? (categories) (if applicable)
20. Is information available on patient complaints on PA-decisions (refusals)? If yes, do you know what the main complaints are? (categories) (if applicable)

Thank you very much for your cooperation.

Annex D Overview of the workshop programme

Agenda Day 1: Implementation of PA-systems	
09.30 – 09.45	Word of welcome by DG SANTE
09.45 – 09.55	Introduction of the study by Ecorys
09.55 – 10.30	Implementation of Prior-Authorisation systems: characteristics
10.30 – 11.05	Implementation of Prior-Authorisation systems: procedures Including good practice presentation: Luxembourg
11.05 – 11.15	Implementation of Prior-Authorisation systems: Prior-Authorisation requests and refusals
11.15 – 11.25	Break
11.25 – 12.15	Underlying reasons for (not) having a Prior-Authorisation system
12.15 – 12.25	Summary and wrap up by Ecorys
12.25 – 12.30	Closing words by DG SANTE
Agenda Day 2: Information provision	
09.30 – 09.45	Word of welcome by DG SANTE
09.45 – 10.00	Recap day 1 & introduction of today's programme
10.00 – 11.00	Information provision: comprehensiveness & comprehensible Including good practice presentation: Ireland
11.00 – 11.15	Break
11.15 – 12.15	The way forward: towards guiding principles for Prior-Authorisation
12.15 – 12.25	Summary and wrap up by Ecorys
12.25 – 12.30	Closing words by DG SANTE



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