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# Policy proposals to improve access to multiple sclerosis treatments in Europe

## Final report

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## Executive Summary

Biogen asked Charles River Associates (CRA) to investigate the different factors that create barriers to patient access to multiple sclerosis (MS) treatments in Europe and to develop a set of credible recommendations to health policymakers at national and EU levels as well as national payers and clinicians, regarding practical measures that could improve access to treatment for MS patients. This includes recommendations on clinical practices as well as overall disease management, healthcare funding and reimbursement restrictions. This research builds on a study conducted by CRA in 2014, which revealed that inequities in access to Disease Modifying Drugs (DMDs) used to treat MS still exist across Europe, with significant variations by country.<sup>1</sup>

To conduct this study, CRA selected seven countries (Czech Republic, France, Germany, Poland, Spain, Sweden, and the United Kingdom) based on differences in access to DMDs; high-level indicators reflecting different approaches to the diagnosis and management of MS; and economic circumstances and geographical spread. CRA developed a set of criteria against which countries can be compared on their management of MS as a whole, based on discussions with MS patient groups and input from the available comparative literature. Specifically this analysis draws upon the Code of Good Practice in MS developed by the European Multiple Sclerosis Platform (EMSP), which set out clear calls to action that aim to improve MS patients' lives and reduce inequalities in their treatment.<sup>2</sup> The code provides us with the high-level benchmark against which each country can be compared for each set of activities. In order to capture a number of different perspectives and collect input at national and sometimes regional levels, we undertook 53 interviews across the selected European countries with a wide variety of stakeholders (both clinical and non-clinical) involved in MS care and policymaking.<sup>3</sup>

### *Patient referral and diagnosis*

The EMSP Code of Good Practice calls for the “provision of a clear, certain diagnosis as early as possible by a neurologist with specialist knowledge in multiple sclerosis”. Through interviews with different stakeholders involved in the management of MS – such as clinicians, payers,

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<sup>1</sup> CRA (2013) “Access to medicines for multiple sclerosis: Challenges and opportunities”, prepared for Biogen Idec. The 2013 CRA report does not provide an in-depth analysis of the extent to which these factors determine access in specific markets or what would need to be done to address them. Therefore the aim of this report is to characterise more precisely the barriers that prevent access to good clinical care in MS – including restrictions in access to innovative therapies – as well as the relative importance of factors that may inhibit patients' access to care.

<sup>2</sup> EMSP(2008). “Code of Good Practice in MS”. Available at: <http://www.emsp.org/wp-content/uploads/2015/07/European-Code-of-Good-Practice-english-version.pdf> [Accessed on 08 October 2015].

<sup>3</sup> This included MS patient associations in each market and their supporting caregivers; healthcare professionals including leading clinicians (e.g. neurologists), primary care providers (PCP) and MS specialised nurses; and also policymakers (e.g. representatives from the Ministry of Health and a Member of Parliament specialising in healthcare issues); funder holders/payers and MS policy experts (e.g. academics or scholars involved in the MS debate). These interviews were undertaken between May and September 2015.

policymakers and patient groups – we explore the wider diagnosis and patient referral process across each of the seven countries. We find significant variation in the speed of diagnosis as well as a range of different barriers. We summarise these findings in Table 1 below:

**Table 1: Key findings on patient referral and diagnosis**

Findings	Countries
Some countries experience delays in referral of patients with suspected MS to a neurologist/MS centre due to lack of awareness of MS symptoms and insufficient training for primary care professionals	 Poland, Sweden, Czech Rep, UK
There is a culture of “watching and waiting” for symptoms to formalise which creates reluctance to refer patients to a neurologist.	 Poland, , UK
There is a difficulty in accessing specialised care due to a shortage of neurologists	 Poland, Sweden, Czech Rep, UK
There are significant variation in the time taken to receive an MRI which is associated with a number of factors including the cost of an MRI and the distribution of MRI scanners across the country	 Poland, , UK, Sweden

Even in countries that experience these problems to a lesser extent (Germany, France, Spain, Sweden, and the Czech Republic), the extent of these barriers still varies significantly by region and particularly depends on patients’ ability to access MS treatment centres. In some countries it depends on the stage of the disease: patients with severe symptoms are diagnosed much faster, typically within a few weeks.

In the UK and in Poland, healthcare professionals perceive the delay in diagnosis as problematic. The delay is largely driven by a lack of specialised neurologists, poor access to MRIs, and slow referral by primary care physicians (PCPs). In Poland, respondents indicated that the mean time from first symptoms to diagnosis is 2.6 years, depending on when a patient presents him/herself in the physician’s office.

*Initiation of treatment and clinical management*

Once patients are adequately diagnosed, the EMSP Code of Good Practice indicates that they should have “timely access to appropriate drugs”. Respondents were asked about the speed with which treatment was initiated and the types of products used, particularly distinguishing symptomatic treatments from disease-modifying drugs.

We find that timely access to appropriate treatment varies widely across the selected countries. Whilst all countries have developed clinical guidelines that provide recommendations on initiation of DMDs and monitoring, not all countries follow guidelines to the same extent, and the degree to which drugs are freely prescribed appears to be a major factor in patient ability to access the right treatment.

In Germany, France, and Spain, guidelines are not mandatory. This also means that neurologists are permitted to prescribe all approved DMDs with no or few reimbursement restrictions. This is linked to greater treatment flexibility and the ability to engage with the patient more attentively when making decisions around treatment options. Rapid initiation of treatment is seen as largely favourable and encouraged in these markets. As listed in Table 2, Poland and the Czech Republic tend to postpone treatment initiation and have introduced strict conditions or other limitations on access to treatment, including: restrictions on the number of MS patients eligible to receive DMD treatment; geographical conditions such as requiring patients to be treated only in a specialised MS treatment centre; and clinical restrictions such as requiring patients to meet certain criteria in order to be reimbursed for DMDs. These restrictions create significant barriers to accessing care and can lead to significant delays in receiving treatment. These delays may have significant impacts on patients’ disease progression and quality of life.

**Table 2: Key findings on treatment initiation and access to innovative therapies**

Findings	Countries
Some countries postpone treatment initiation due to clinical pre-conditions – patient must demonstrate active MS, relapsing onset. i.e. only patients with RRMS, CIS, or the first phase of SPMS.	 Poland, Czech Rep, UK
There are strict conditions or other limitations on access to treatment, e.g. restrictions on the number of MS patients; geographical conditions; and clinical restrictions	 Poland, Czech Rep,
There are limits on the types of medications MS patients have access to i.e. innovative medicines, off label use of treatments	 Poland, Czech Rep, UK
There are delays in accessing innovative treatment due to formal reimbursement procedures	 Poland

*Ongoing management of MS*

Good coordination between healthcare professionals as well as between the patient and healthcare professionals is another essential criterion for effective and timely care. The EMSP Code of Good Practice states that patients should be included within an interdisciplinary team of healthcare professionals and this should be coordinated by a single health professional who also acts as a “reference person” for the patient. We investigate the wider management of MS through patient follow-up, treatment maintenance, organisation of care, the role of different specialists, and the significance of a multidimensional team. We find that the wider management of MS varies widely across the seven countries. We summarise key findings in Table 3 below. Whilst patient follow-up and maintenance treatment are similar across all of the countries studied, with regular clinical monitoring at relapses and clear guidelines to switch therapies, there are important differences in the organisation of care, and in the roles and the

coordination of different MS specialists – which lead to important differences in access to follow-up treatment and maintenance treatment:

- Role of the neurologist, PCP and MS nurse: We find that neurologists are much more involved in guiding treatment choices and ongoing management of patient care in some countries – namely Sweden, the Czech Republic, Spain, and to some extent, France – than in others. In Germany, the role of the PCP is much more important, and the PCP can assume responsibility for some of the oversight and ongoing prescriptions, although not for initiating therapy or diagnosis. Similarly, the role of specialised MS nurses also varies widely, from providing information and education to MS patients and their families to coordinating and organising care for patients. In all countries, specialised MS nurses have played a key role in ensuring appropriate communication with patients to support them in managing their disease. In the UK, their role also often involves coordinating the effective management of patient care.
- Coordination of MS specialists: Germany and the Czech Republic, have developed acute care centres that specialise in the treatment of MS. These centres hold specific multidisciplinary MS teams, which consolidate the range of skills necessary to ensure the continuum of care, although capacity of these centres remains an issue in the Czech republic, which restricts access for some patients. In contrast, France has opted for a decentralised approach through the development of “MS networks” (“Reseaux SEP”) to ensure coordination of care for people with MS. This has provided an effective mechanism to ensure greater levels of communication and coordination in the outpatient setting, thereby facilitating patient access at the local level.

According to the EMSP, patient registries are also crucial to feed into the organisation of MS treatment (and further research on MS). There have been clear efforts across countries over the years to establish MS registries. Though none of the registries provide a comprehensive coverage of all MS patients, their initiation by various stakeholders – academic institutions, professional and patient organisations – illustrate that there is widespread recognition of the need for data collection. Registries are much more developed in France and Sweden, two countries which pioneered patient registries for MS. These national efforts have now turned to the development of registries at European level such as the EDMUS project (European Database for Multiple Sclerosis) in order to create a database of MS patient data that uses a common language in patient files and makes it easy to select, exchange, compare and share data and files. This has greatly facilitated the monitoring of patients and the exchange of information among physicians.<sup>4</sup>

As MS progresses, patients need complementary care services to address and manage MS associated symptoms and disability. The EMSP Code of Good Practice states that a patient should have access to non-pharmacological therapies and rehabilitation services (which includes neurology, rehabilitation medicine, nursing, physiotherapy, clinical psychology, social counselling, occupational therapy and speech therapy) throughout the patient’s life, as their

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The EDMUS project website. Available at: <http://www.edmus.org/en/proj/index.html> [Accessed on 06 October 2015].

omission “severely diminishes the quality of life” and can “lead to missed opportunities to more effectively manage the progression of the disease”<sup>5</sup>. We find that in the majority of countries, access to complementary healthcare services – such as rehabilitative care, physiotherapy, and palliative care – varies widely across patients and across regions. Even in wealthier countries such as Sweden, access to these types of resources is limited and depends heavily on geographic location and access to MS treatment centres. In the UK, where social care services are funded by local authorities, there are strong variations in access to complementary care services. Generally, there is greater service ability in urban environments compared to rural areas, where there are fewer healthcare professionals. While there are many factors contributing to the variation in complementary care services, the lack of integration between health and social care is certainly problematic. For instance, healthcare in Sweden is the responsibility of the county, whilst social care is the responsibility of the municipality. In situations such as these, patients may be shifted back and forth between different organisations, resulting in poor coordination of services and huge delays in access to rehabilitation and palliative care.

**Table 3: Key findings on ongoing management of MS**

Finding	Countries
Neurologists are heavily involved in guiding treatment choices and managing patient care	 Czech Rep, Spain, France
Specialised MS nurses take a leading role and are instrumental in coordinating and organising patient care	 UK, Sweden, Germany
Some countries provide care within specialised MS care centres which integrate all medical services	 Germany, Czech Rep, UK
In other countries, care is being provided within both hospital and ambulatory settings, but coordination of care remains a significant issue	 Spain, Poland, Sweden, France
Some countries still lack fully fledged MS patient registry	 Germany, UK, Poland, Spain

<sup>5</sup> EMSP (2008) “Code of Good Practice in MS”. Available at: <http://www.emsp.org/wp-content/uploads/2015/07/European-Code-of-Good-Practice-english-version.pdf> [Accessed on 08 October 2015].

In some countries, physiotherapy and rehabilitative care is difficult to access and is either under-prescribed by neurologists or geographically restricted 

Spain, Poland, Sweden, France

*Resources allocated to the treatment of MS*

Providing MS care requires significant resources. We compare the amount of resources allocated to the treatment of MS across the seven countries. Whilst health budgets have been increasing in most countries, the level of resources allocated to MS has not kept pace with the rising cost of new innovative therapies. Lack of resources was stated to be a particular problem in the Czech Republic and Poland, where respondents indicated this as being the main barrier to access to MS care. The issue of resources appears to be an even greater challenge at regional level, where countries with decentralised health funding such as Poland, Spain, and Sweden – reported in the interviews important differences in resources and funding between regions, leading to important differences in access within a country. In order to address this challenge, some countries have introduced regional adjustments in funding.

**Table 4: Key findings on resources and financial coverage**

Finding	Countries
The budget allocated to MS was seen as insufficient resulting in a high number of untreated patients	 Czech Rep, Poland
There are important differences in resources and funding between regions, leading to important differences in coverage within a country	 Poland, Spain, Sweden
Some countries have little or no co-payment to access clinical MS care	 Germany, UK, Poland, Czech Rep
Other countries have some levels of co-pay but this remains relatively low and is not seen as a significant barrier to access	 Sweden, Spain, France

*Identifying the challenges to access along the care pathway*

Based on the assessment of good practice, we find that there are differences between countries in the management of care as well in the policies that have been implemented. We apply these lessons to the care pathway in each of the case study countries and explore where the challenges lie and to what extent these existing good practices can be leveraged on a country by country basis.

- Czech Republic: Barriers to access in the Czech Republic occur across the entire care pathway but can be found largely at the early stages – at the referral and diagnosis stage and also at the stage where treatment is initiated. This can be largely attributed

to financial constraints associated with budget restrictions in hospitals and other MS specialised care centres. Financial constraints translate into delays in access to MS centres, restricted access to treatment, and stringent treatment with little flexibility in treatment choice. Once the patient is diagnosed and put on treatment, access to multidisciplinary care and patient follow-up is efficient, and complementary care services are accessible, although this can vary widely across regions.

- France: There was general consensus amongst respondents in France that MS care is relatively well structured and there are few barriers at the early stage of the care pathway. Patients get referred to a neurologist and diagnosed relatively quickly compared to patients in other European countries. Initiation of treatment is also relatively swift, and French patients benefit from timely access to appropriate drugs with a wide flexibility around treatment options. France appears to be experiencing challenges in ensuring the continuity of care post-diagnosis. Patient follow-up and access to complementary care such as palliative care is not well structured and lacks a clear focal point or reference person for the MS sufferer.
- Germany: There are few barriers to access to MS care in Germany. Patients are diagnosed relatively quickly thanks to a large network of neurologists and adequately trained PCPs. Reimbursement of MS treatment is good, with few restrictions; follow-up care is well structured; and there are few barriers at the early stage of the care pathway. However, as in many other European countries, access to rehabilitative care and other complementary care services is under-prioritised, and access to these will vary widely depending on the region as well as on differences in reimbursement conditions contingent on a patient's health coverage.
- Poland: There are many barriers to access to treatment in Poland, starting with slow and inefficient referral and diagnosis. Still relatively little is known about MS at the primary care level, even though the disease is gaining coverage. Lack of resources means that the diagnosis remains slow and there are significant delays in putting patients on adequate treatment. Budgetary restrictions have also led to the introduction of restrictions on the number of patients, on the types of treatment options available, and on the length of time that patients can remain on treatment (5 years for second-line treatment). These restrictions are some of the key factors limiting access to MS treatments in Poland. Once patients are registered on the drug programme and enrolled in treatment, Key Opinion Leaders (KOLs) in Poland indicated that clinical management of the disease and patient follow-up is more acceptable, although many KOLs expressed concerns about the lack of innovative first-line treatment options. It was also acknowledged that there is a need to improve rehabilitation and palliative care for MS patients in Poland, and more adequate resources need to be allocated to support the continuum of care including social care in general.
- Spain: Access to MS care in Spain is relatively well structured and there are few barriers at the early stage of the care pathway. Diagnosis and initiation of treatment is conducted reasonably quickly and this was not necessarily seen as a significant barrier. Once diagnosed, there are relatively few restrictions and limitations to accessing treatment, although access to treatment and care services can vary widely

across regions. The Spanish health system is devolved, and each of its 17 regions has its own responsibility to regulate healthcare policy; planning and provision; and clinical guidelines, which can lead to important variations in access to care.

- Sweden: Due to a relatively well funded healthcare system, there are comparatively few barriers to access to pharmaceutical treatment in Sweden. However, a chronic lack of PCPs and neurologists in some areas of the country creates delays in obtaining a formal diagnosis. Once diagnosed, patients have access to relatively good care and to innovative treatment albeit within strict conditions. There are wide variations in access to care, and evidence on challenges associated with MS care in Sweden varied greatly amongst individuals we interviewed. A lack of coordination between health and social care, despite efforts to integrate them, remains a distinct challenge for patients.
- United Kingdom: Many of the 2014 MS report findings still apply to the UK. The delay in receiving a clear diagnosis was perceived as one of the main barriers by healthcare professionals and other stakeholders in the UK, who recognised the importance of diagnosing MS rapidly and initiating treatment early but also acknowledged the number of hurdles to overcome in achieving this. Lack of understanding and awareness of MS symptoms by PCPs who are not sufficiently trained to recognise them certainly contributes to this problem. Shortage of specialised neurologists and important variation in the time needed to receive an MRI are also important factors. Despite having adequate coverage of MS treatment in the UK, patient access to DMDs is low. Whilst clinical guidelines provide recommendations on the use of adequate treatment, multiple documents around the use DMDs and clinical management of MS are developed separately and are often inconsistent. Despite this, some respondents also indicated some level of “patchiness” in neurologists’ knowledge of the available MS treatments, particularly the newer therapies. This exacerbate the variation in treatment across the healthcare system and leads to heterogeneous treatments pathways and prescribing practices. Once on treatment, despite an effective system of MS specialised nurses who effectively oversee a patient’s care, the lack of “comprehensive collaboration” between different healthcare units for MS was also suggested as an important barrier to optimum patient treatment and follow-up. Finally, we observe that the UK still lacks a national MS patient registry to ensure that resources are allocated adequately and the evolution of the disease burden is monitored.

*Good practice examples*

Finally, drawing from this analysis of each country, we set out some of the good practices examples, where countries have adopted different policy initiatives to improve access along the care pathway.

**Table 5: Good practice examples on referral and diagnosis**

Practice	Good examples
Introduce an educational component (training programme) to increase disease awareness and improve the degree of referrals.	 France, Germany
Improve access to specialised neurologists and invest in MRI machines, particularly in rural areas.	 Germany

**Table 6: Good practice examples on initiation of treatment**

Practice	Good examples
Develop appropriate clinical guidelines that provide clear and comprehensive recommendations on DMD initiation and monitoring to address specific patient needs.	 UK
Reduce reimbursement restrictions and limitations on access whilst promoting and monitoring appropriate use of medicines.	 Spain, France, Germany
Develop scheme to provide temporary access to new treatments whilst new treatments are being reviewed/authorised.	 France, Germany

**Table 7: Good practice examples on ongoing management of MS**

Practice	Good examples
Designate a clear point of contact responsible for the patient in order to ensure patient-centred care.	 Germany, Sweden, Czech R
Leverage specialised MS nurses appropriately to ensure adequate coordination and the management of care for the patient.	 UK, Sweden
Further develop specialised MS care centres through the use of acute care centres specialised in the treatment of MS with a specific MS team.	 Czech Rep, Germany

Encourage multidimensional team with smooth communication through formalising professional networks, to organise and facilitate the complementarity and coordination of all respondents involved in the care for people with MS.	 France
Collect patient data through registries/databases, which can provide sufficiently detailed information on the provision of treatments and services as well as monitor the situation of MS patients over time.	 France, Sweden
Integrate health and social care services and funding to ensure that patients get the right care and support at any point in their care journey.	 Scotland

**Table 8: Good practice examples on resources and financial coverage**

Practice	Good examples
Develop complementary sources of funding for rehabilitation and disability support and social aid programmes.	 Poland
Introduce special coverage protocol for chronic conditions that require ongoing long-term care.	 France

*Applicability to the wider European setting.*

Drawing on the best practices highlighted above and some of the findings and conclusions from this survey, we attempt to assess the extent to which these conclusions can be used in other countries and how these recommendations can be applied and leveraged by other healthcare systems across Europe. We developed a set of country archetypes which allows us to connect the findings from this survey to produce a set of clear country specific recommendations for a broader set of countries.

- Western European countries with social health insurance system (e.g. Belgium, Austria) are characterised by private provision of care often which generates difficulties in ensuring adequate patient access to complementary care such as rehabilitation and palliative care which often lacks a clear focal point or reference person. These countries should seek to accentuate effort on coordinated approach to care and ensure a more homogeneous coordination of all stakeholders.
- Nordic countries (Denmark, Finland, and Norway) have similar characteristics in terms of the wide geographical variations that they experience in access to care and the lack of PCPs and neurologists in some areas of the country. One priority should be to support the development of infrastructure to enable patients in rural settings to be diagnosed in a timely manner and continue the closer integration of clinical care and social care services for MS patients.

- The Spanish health system like the Italian system is regionally devolved, and each region has its own responsibility for planning, provision and funding of care can lead to important variations in access to care across the country. The development of a coherent set of policies will help streamline the provision of care across the country and ensure timely and appropriate use of treatment options.
- Central and Eastern European countries (Romania, Slovenia) like Poland and the Czech Republic generally experience restriction on access to treatment largely due to lower levels of spending on healthcare. Raising physician awareness of the need to diagnose and treat MS early to overcome barriers to fast neurologist consultation for non-emergency patients along with greater investment to support development of infrastructure and greater funding for MS will improve access and eliminate restrictions on the number of patients with MS eligible to receive DMD treatment.

### *Conclusions*

Improving access to treatments for patients with MS requires a holistic view of how patients are diagnosed, how treatment is initiated, and how the disease is managed on an ongoing basis, as well as a view of the required resources. Drawing on the perspectives of all the stakeholders involved helps us to understand the bottlenecks and barriers restricting access to treatment today and provides useful lessons from different policy initiatives across Europe. These are the key inputs into developing country specific policy proposals.

This report looks at the assessment of good practice, the differences in management of care between countries, and the policies that different countries have implemented, all of which provide useful lessons. These lessons then be applied to the care pathway in each of the case study countries, exploring where the challenges lie and to what extent these existing good practices can be leveraged on a country by country basis.

## 1. Introduction

Biogen asked Charles River Associates to investigate the different factors that create avoidable barriers to patient access to multiple sclerosis (MS) treatments in Europe. This report aims to develop a set of credible recommendations – to health policymakers at national and EU level as well as national payers and clinicians – on practical measures that could improve access to treatment. This research focuses on the following:

- Identifying specific avoidable barriers to patient access to MS therapy in different European countries – such as clinical practices and overall disease management, healthcare funding or reimbursement restrictions.
- Examining what constitutes good practice from the perspective of the MS patient community in terms of general access to clinical care as well as more specific access to available treatments.
- Describing potential reforms and system improvements which will enable/facilitate better access to treatment and disease management for MS patients that can be leveraged by policymakers across the many different EU national markets, and the benefits these would bring.
- Setting out how individual countries can change current policies to improve MS care and health outcomes for patients by drawing on these good practices while taking into account the specific characteristics of the market.

A preliminary version of this report was presented at the Biogen Patient Advocacy Summit in Barcelona in October 2015, with about 25 senior patient advocacy leaders from across Europe. Comments from that meeting along with additional contributions from patient associations from across Europe were collected and incorporated in this final report. We would like to thank the European Multiple Sclerosis Platform (EMSP) and its members for their active participation in contributing to this research.

### 1.1. Background

In 2013, CRA undertook a study for Biogen examining the extent to which access to MS treatments has changed in Europe, particularly as a number of new MS treatments had recently been launched.<sup>6</sup> The study revealed that there are still important inequities in access to Disease Modifying Drugs (DMDs) used to treat MS across Europe, with significant variations by country (see Figure 1). It also found that people with MS are often unable to obtain the treatments they and their doctors believe would offer the best clinical outcomes.<sup>7</sup>

The report concluded that whilst these medicines can help to slow down the progression of MS for many years, access to such treatments continues to depend on where the patient lives and

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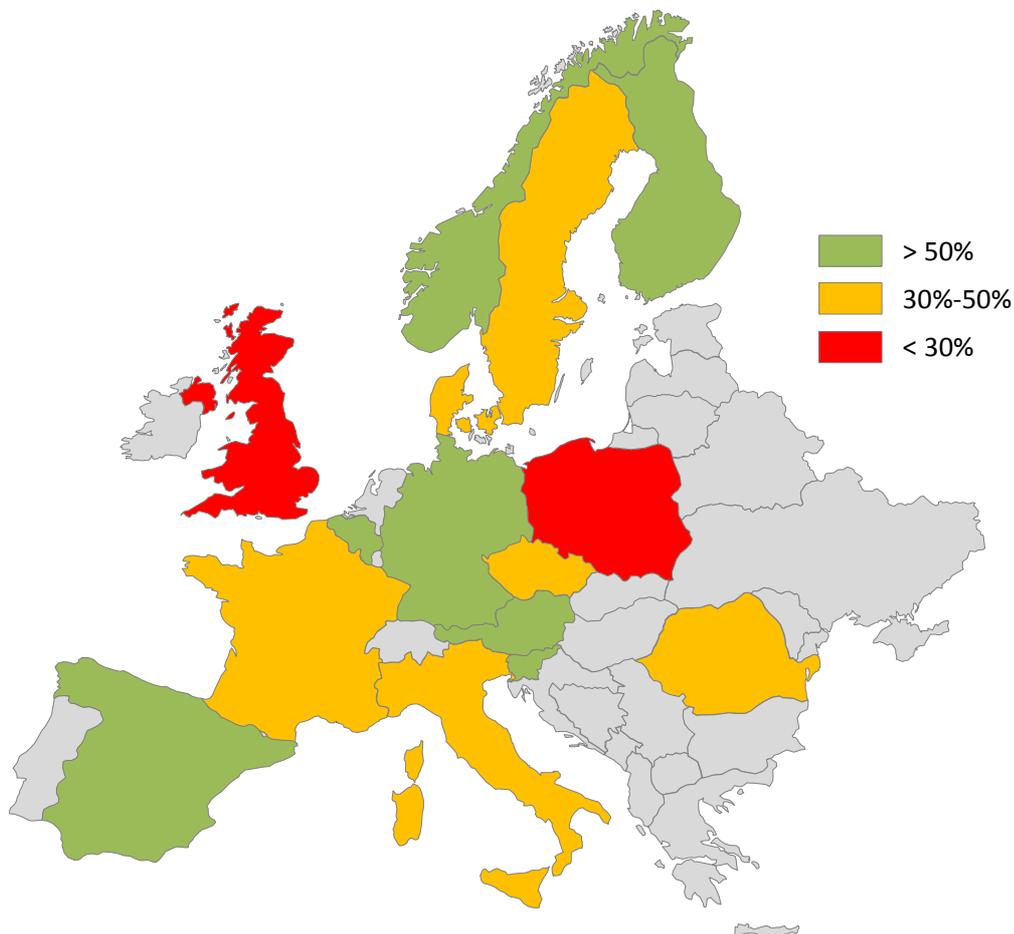
<sup>6</sup> CRA (2013) "Access to medicines for multiple sclerosis: Challenges and opportunities", prepared for Biogen Idec

<sup>7</sup> Ibid.

the policies adopted at a national and regional level for the diagnosis, classification and treatment regimens for MS as the condition progresses.

Although there are significant challenges with collating like-for-like statistics, we used a pragmatic approach to show how the approach to treatments and social care varies substantially throughout Europe, with access to modern DMDs being as high as 69% in Germany but only 13% in Poland. The report also found that even within countries, there are often substantial variations, region by region, in the degree of access to DMDs, depending upon locally agreed policies for funding of these medicines and what is perceived to be best clinical and social care practices.

**Figure 1: Proportion of total MS patient population receiving DMDs in selected European countries (2013)**



Source: CRA analysis using IMS 2013, local MS societies, MS Atlas 2013, GERS (France), Farmastat (Norway)

Based on statistical data, CRA reached some high-level conclusions as to what factors were driving these trends. The CRA report discussed the importance of different approaches to diagnosis and clinical management, to funding, and to the process for assessing innovative medicines and affordability. However, the report did not provide an in-depth analysis of the

extent to which these factors determine access in specific markets and what would need to be done to address the various barriers to access.

More generally, whilst there is a large literature focusing on improving clinical practices of MS such as revising diagnostics<sup>8</sup> or improving quality of life for people with chronic conditions,<sup>9</sup> few articles provide a holistic assessment of how healthcare systems respond to patient needs and ensure adequate treatment is provided for MS patients.<sup>10</sup>

The aim of this report is to characterise more precisely the barriers that prevent access to good clinical care in MS, including restrictions in access to innovative therapies. Although the report looks at provision of care to MS patients in general, it is mostly focused on patients with Relapsing Remitting MS (RRMS), for which the majority of DMDs are most commonly used. It also examines the relative importance of factors that may inhibit patients' access to care (including funding restrictions, sub-optimal disease management, and lack of adequate information to ensure effective decision-making) and the extent to which alternative reforms have improved access to care from both a clinical and a non-clinical perspective. We then consider the degree to which it is possible to leverage good practices from across the healthcare systems across Europe.

This report is not intended to be a comprehensive examination of medical practice in MS nor a systematic survey of MS care management activities throughout Europe. Its purpose is to provide an overview of the strengths and weaknesses of different international approaches from the perspective of the MS stakeholder community. This covers both clinical care and wider disease management as well as what these suggest in terms of possible improvements in MS care and health outcomes for patients, and where policy initiatives could improve patient access.

## 1.2. Methodology

The research was conducted using the following three-step approach:

In Step 1, we focus on identifying appropriate case study countries. Drawing on the first study by CRA and a number of international surveys including material developed by a patients'

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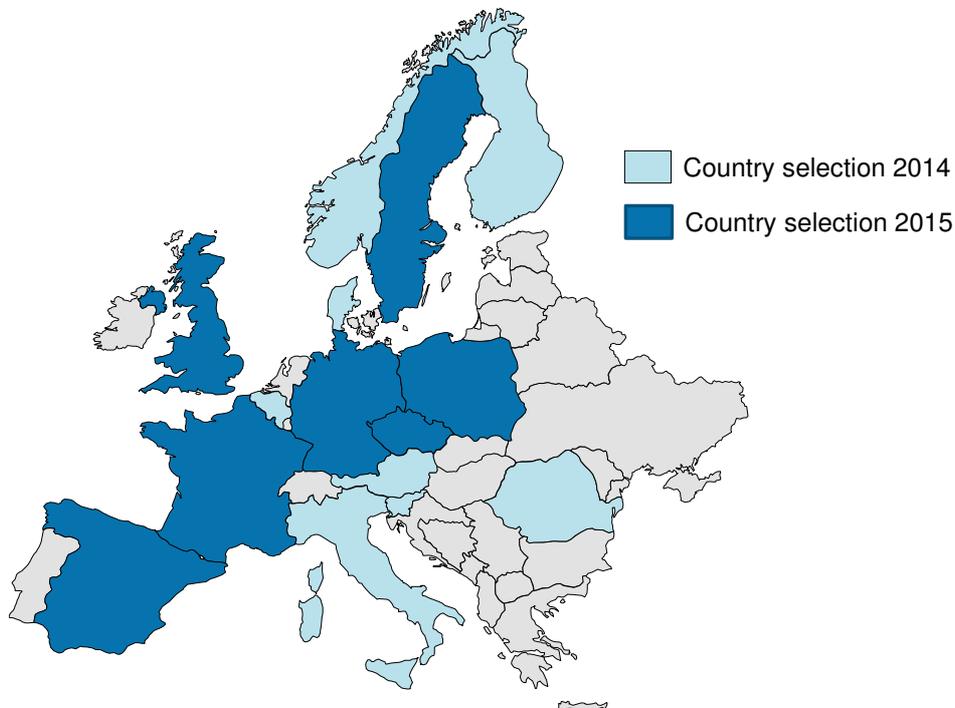
8 Polman, C. H., Reingold, S. C., Edan, G., Filippi, M., Hartung, H. P., Kappos, L. ... & Wolinsky, J. S. (2005). "Diagnostic criteria for multiple sclerosis: 2005 revisions to the 'McDonald Criteria'". *Annals of Neurology*, 58(6), 840-846.

9 Husted, C., Pham, L., Hekking, A., & Niederman, R. (1999). "Improving quality of life for people with chronic conditions: the example of t'ai chi and multiple sclerosis", *Alternative therapies in health and medicine*, 5(5), 70-74.

10 For example, in the UK, the national audit of services for people with multiple sclerosis 2011 has carried out a clinically led audit of the organisation, resourcing and performance of NHS services for people with multiple sclerosis (MS) in England and Wales. The audit measures how the NHS fares against the standards embedded in the NICE clinical guideline Management of multiple sclerosis in primary and secondary care.  
[https://www.rcplondon.ac.uk/file/957/download?token=x4\\_c7eHX](https://www.rcplondon.ac.uk/file/957/download?token=x4_c7eHX)

organisation (the MS Barometer of the European Multiple Sclerosis Platform (EMSP)<sup>11</sup>) as well as discussion with MS patient groups, it is clear that treatment varies in a wide range of dimensions. CRA selected seven countries based on differences in the selected diagnostic and management indicators (for number of health professionals/teams; delay to MRI and diagnosis; availability of treatment; standard treatment criteria; existence of MS registries; and delay to treatment) and also based on economic circumstance (i.e. countries representing a range of income levels) and geography (countries representing different regions in Europe e.g. Northern/Central Europe). The following seven countries were selected: Czech Republic, France, Germany, Poland, Spain, Sweden, and the United Kingdom.<sup>12</sup> Figure 2 below illustrates the countries studied as part of the 2014 MS access report (light blue) and those selected as part of this study.

**Figure 2: Country coverage in 2014 MS report vs 2015 report**



Source: CRA analysis

In Step 2, we develop a set of criteria against which countries can be compared on their management of MS as a whole, based on discussions with MS patient groups and input from

<sup>11</sup> EMSP (2013) "MS Barometer 2013: Widespread health inequalities revealed". Available at: <http://www.ms-sep.be/userfiles/files/emsp/MS%20Barometer%202013.pdf> [Accessed on 06 October 2015].

<sup>12</sup> In reality, the healthcare system in the United Kingdom is devolved to the constituent countries. We have noted where policies or data apply specifically to a particular country.

the available comparative literature (e.g. the Atlas of MS<sup>13</sup> and EMSP's Barometer) as well as found on the websites of patient organisations. Most significantly, we draw upon the practices developed by EMSP,<sup>14</sup> an umbrella organisation representing MS societies across Europe, to improve access to quality treatment for MS patients. The ESMP's Code of Good Practice,<sup>15</sup> along with several consensus documents on the management of MS, provides a practical framework that describes consensus-based agreement from across Europe on the optimal approach to care for MS patients in relation to treatments, therapies, services, research, employment, and patients' empowerment. The document contains a list of provisions needed to ensure "Equal Rights and access to treatment, therapies and services in the management of Multiple Sclerosis", including those listed in Table 9. For each, CRA has developed a set of topics for further assessment.

**Table 9: CRA assessment topics against selected EMSP "Good Practice"**

Selected EMSP Good Practice	Assessment topics
<b>The provision of a clear, certain diagnosis as early as possible by a neurologist with specialist knowledge in multiple sclerosis</b>	Average period of diagnosis Number of early diagnoses
<b>Referral to a specialist neurological rehabilitation team, which should recognise the varying and unique needs and expectations of each person affected by MS.</b>	Number of specialist neurological services Average referral time Access to specialist neurological services
<b>Timely access to appropriate drugs according to latest results of scientific research.</b>	Factors that contribute to the decision to initiate treatment , such as: <ul style="list-style-type: none"> <li>• treatment guidelines,</li> <li>• eligibility criteria for access to medicines,</li> <li>• understanding of the urgency to treat,</li> <li>• the role of patient choice, and</li> <li>• the willingness to initiate treatment even before a clinically definitive diagnosis.</li> </ul>

<sup>13</sup> MSIF (2013) "The Atlas of MS 2013, Mapping multiple sclerosis around the world". Available at <http://www.msif.org/about-us/advocacy/atlas/> [Accessed on 06 October 2015].

<sup>14</sup> About EMSP <http://www.emsp.org/>

<sup>15</sup> European Multiple Sclerosis Platform (2008). "Code of Good Practice in MS". Available at: <http://www.emsp.org/wp-content/uploads/2015/07/European-Code-of-Good-Practice-english-version.pdf> [Accessed on 08 October 2015].

<b>Inclusion within this interdisciplinary team of healthcare professionals</b>	<p>Maintenance of treatment and the roles of different specialists and a multidimensional team with fluid communication</p> <p>Ensuring adherence, including approaches to monitor the effectiveness of the treatment on patients.</p> <p>Approaches to managing tolerability</p>
<b>Health services must have the capacity to respond in a timely manner without excessive delay and bureaucracy.</b>	<p>The amount of resources allocated to the treatment of MS and other economic factors such as the relative price of new treatments and affordability of MS specific therapies (e.g. DMDs) by patients across Europe.</p>
<b>Later, at the onset of greater impairment, the development of a personalised symptom and disability management programme co-developed by the person affected by MS and his/her specialist team.</b>	<p>Extent to which treatment is provided flexibly, taking into account the heterogeneity of the disease (with disease progression varying depending on age of onset, apparent disease severity), or whether rigid guidelines are followed.</p>
<b>At advanced stages, adequate and appropriate community care services including home adaptations, assistive technologies and technical aids and supported housing to enhance mobility and independence.</b>	<p>The availability of complementary healthcare services such as community care services, rehabilitation, palliative care etc.</p>

Source: CRA analysis based on EMSP (2008). "Code of Good Practice in MS".

In Step 3, we investigate the conditions under which patients have access to treatment, the organisation of the healthcare system, and the implication for funding and sustainability in each of the selected countries. Based on the criteria in step 2, CRA developed a structured questionnaire to facilitate interviews with stakeholders. The questions were designed both to capture the stakeholder's high-level views on strengths and weaknesses of different approaches (i.e. what is considered to work effectively from both a clinical and non-clinical perspective) and to elicit responses on specific detailed measures/practices and collect evidence on each measure's effectiveness and impact on patients and the wider healthcare system. This served not only to capture the individual elements that can affect MS patients' treatment but also to discuss how the individual elements need to fit together. In order to gather a number of different perspectives, CRA interviewed a set of stakeholders involved in MS care and policymaking. This included MS patient associations in each market; healthcare professionals including leading clinicians (e.g. neurologists), primary care physicians (PCP) and MS specialised nurses; policymakers (e.g. representatives from the Ministry of Health or a member of parliament specialised on healthcare issue); funder holders/payers and MS policy experts (e.g. academics or scholars involved in the MS debate).

In total, CRA conducted 53 interviews across the selected seven European countries. These are summarised in the table below.

**Table 10: Interviews conducted<sup>16</sup>**

Country	Patient associations	Neurologists	PCPs	MS Nurses	Other Specialists	Payers	Policy makers	Policy experts	Total
<b>Czech Republic</b>	1	2	1			3			7
<b>France</b>	2	2			1	2		1	8
<b>Germany</b>	1	2	1			2			6
<b>Poland</b>	2	2	1			1	2		8
<b>Spain</b>	1	2			1	1	1	1	7
<b>Sweden</b>	1	2		1		2	1		7
<b>United Kingdom</b>	2	2		1	1	2	1		9

### 1.3. Structure of the report

The rest of the report is structured as follows:

- Chapter 2 looks at how different countries diagnose MS and the barriers to referrals.
- Chapter 3 reviews the factors that contribute to the decision to initiate treatment.
- Chapter 4 examines the differences in ongoing treatment and management of MS across the selected case study countries.
- Chapter 5 considers the implications for resourcing.
- Chapter 6 draws together the policy implications for the seven countries included in the report and the extent to which the results are transferable to other markets.

<sup>16</sup>

Not all stakeholders were interviewed in all countries. This is largely due to major differences in the care dynamics of the individual countries. CRA selected 7-8 of the most relevant stakeholders for each country.

## 2. The referral and diagnosis process

We begin by considering the different approaches countries take to diagnosing MS, using EMSP's Code of Good Practice in MS<sup>17</sup> as the benchmark against which to compare the activities and organisation of care in each of the selected countries.

Diagnosis is a key factor that affects treatment initiation and overall disease management. The EMSP Code of Good Practice calls for the "provision of clear, certain diagnosis as early as possible by a neurologist with specialist knowledge in MS".<sup>18</sup>

There are a variety of approaches to diagnosing MS, including the McDonald criteria, the Poser criteria, and the Schumacher criteria.<sup>19</sup> The McDonald criteria, first published in 2001, were last revised in 2010 and have replaced the older MS diagnostic criteria such as the Schumacher criteria and the Poser criteria.<sup>20</sup> According to our interviews, all countries studied use the McDonald criteria for diagnosis.<sup>21</sup> The McDonald criteria differentiate between Relapsing Remitting MS (RRMS) and Primary Progressive (PPMS) through evidence that central nervous system (CNS) lesions are disseminated in space (DIS) and in time (DIT), demonstrated by MRI, whilst the Poser criteria do not. The EMSP guidelines do not set out good practice for diagnostic tools although they do refer to the McDonald criteria as diagnostic criteria and the need to establish diagnosis early with high reliability given the availability of DMD therapies.

This section explores the wider process of diagnosis and examines barriers to rapid diagnosis, particularly access to specialists. We find this varies significantly between countries and even between different patient populations (urban and rural, for example) in the same country. In making this comparison, we distinguish between:

- the role of PCPs in referring to appropriate specialised care
- the role of neurologists
- the use of diagnostic tools, such as MRIs.

<sup>17</sup> EMSP's Code of Good Practice in MS presents the current issues facing people with multiple sclerosis, and those who care for them, and sets out clear calls to action aimed at improving their lives and reducing health inequalities.

<sup>18</sup> EMSP (2008) "Code of Good Practice in MS". Available at: <http://www.emsp.org/wp-content/uploads/2015/07/European-Code-of-Good-Practice-english-version.pdf> [Accessed on 08 October 2015].

<sup>19</sup> Selchen et al. (2012) "MS, MRI, and the 2010 McDonald criteria: a Canadian expert commentary", *Neurology* 79(23); McDonald et al. (2001); Recommended diagnostic criteria for multiple sclerosis: guidelines from the international panel on the diagnosis of multiple sclerosis", *Ann Neurol* 50.

<sup>20</sup> MultipleSclerosis.net (2013) "McDonald Criteria for MS".

<sup>21</sup> MSIF (2013) "The Atlas of MS 2013, Mapping multiple sclerosis around the world". Available at <http://www.msif.org/wp-content/uploads/2014/09/Atlas-of-MS>. [Accessed on 06 October 2015].

## 2.1. The role of healthcare professionals in diagnosing MS

According to the EMSP Code of Good Practice, “referral to a specialist neurological rehabilitation team ... should recognise the varying and unique needs and expectations of each person affected by MS”. The EMSP Consensus Paper also recommends “referral of patients to an MS centre following the first symptoms suggestive of MS and once yearly thereafter in case of imminent therapeutic decisions, in case of recurrent infections, unusual complications and poor compliance with medication”.<sup>22</sup> The EMSP does not specifically define how quickly a patient should be seen by a neurologist. We assess how the referral process and timeline varies across the selected countries.

### *Primary care physicians*

The first contact with the healthcare system is typically initiated by the patient, who visits a primary care physician (PCP).<sup>23</sup> Across all countries, respondents reported that patients often delay visiting their PCP especially if their symptoms are mild. The diagnosis process begins with a clinical examination of the patient by the PCP, who will take into account both the reported disorders of the patient and the observable symptoms (troubled vision, clumsiness, etc.) and will review the patient’s neurological history and family medical background.

In all seven countries, respondents indicated that a patient’s severity of symptoms is a key factor affecting time to referral. In particular, less severe symptoms such as fatigue, weakness, numbness and tingling can often be overlooked, leading to some delays in referral to a neurologist or to an MS centre. However, the likelihood of a prompt referral varies across countries. Respondents in the UK indicated that the examination of patient medical history and the referral to a neurologist or MRI is often delayed.<sup>24</sup> These respondents in the UK attributed the delays to the culture of “watching and waiting”, which creates reluctance to refer patients to a neurologist.

The level of awareness of MS amongst PCPs varies from country to country as well as within countries. This will impact their ability to recognise MS symptoms and in turn the timely referral of a patient with suspected MS to a neurologist/MS centre. In Poland, Czech Republic, Sweden and the UK, physicians and other Key Opinion Leaders (KOLs) indicated that PCPs are not well trained to recognise MS symptoms<sup>25</sup> and as a result, referrals to neurologists are further delayed (often referrals are to specialists that address specific symptoms of MS – for example, ophthalmologists rather than neurologists).<sup>26</sup>

22 EMSP (2008) “Consensus Paper II: Basic and escalating immunomodulatory treatments in Multiple Sclerosis”.

23 Apotheken Umschau. “Multiple Sklerose (MS): Diagnose”. Available at: [http://www.apotheken-umschau.de/Multiple-Sklerose/Multiple-Sklerose-MS-Diagnose-18894\\_5.html](http://www.apotheken-umschau.de/Multiple-Sklerose/Multiple-Sklerose-MS-Diagnose-18894_5.html) [Accessed 06 October 2015].

24 Interview with UK neurologist; interview with UK payer.

25 Interview with Czech PCP; interview with Polish patient group.

26 Interview with UK neurologist.

In Germany, Spain and France, both PCPs and neurologists are seen as adequately trained to diagnose MS; however, the final diagnosis is usually undertaken by a neurologist. In the majority of cases of patients with suspected MS, the PCP makes a referral to a neurologist who confirms the diagnosis.<sup>27</sup> These countries indicated that delays to referral are minimal as PCPs are generally more aware of MS today than in the past thanks to MS educational component(s) in their medical training.<sup>28</sup> French respondents indicated that the awareness of PCP has improved significantly in some regions following the introduction of formal MS training, including PCP training, through the recently introduced “MS network”. However, the availability of the training varies by region and largely depends on the level of deployment of the local MS network. Whilst training is available, uptake of such training is dependent on a PCP’s own interest, and referral speed often depends on the existing links between PCPs and neurologists. In all countries, respondents felt that more could be done to help PCPs recognise the potential for MS where patients present with less obvious symptoms, especially given the lack of formal physician training on MS.

### *Neurologists*

Neurologists are typically responsible for the diagnosis and for initiating the patient’s MS treatment. In four of the seven countries studied (i.e. Czech Republic, Poland, the UK and Sweden), access to a neurologist is seen as particularly problematic and in some cases as a hurdle to rapid diagnosis, although this varies widely by region. There are several underlying causes:

- The number of neurology consultants in the UK and Sweden is relatively low, and although this has increased, it was still a concern for respondents in our survey. Indeed, they reported that “access to a general neurologist was difficult and even more so to see a specialised MS neurologist, and obtaining an appointment with a neurologist can sometimes take several weeks/months, and waiting times vary greatly from one city to another”.<sup>29</sup> This is consistent with the data in previous reports showing that in the UK, the availability of neurologists has risen from 1 per 200,000 people in 1998 to 1 per 100,000 in 2013 but remains substantially lower than in other European member states.<sup>30,31</sup> Similarly in Sweden, whilst hospitals must guarantee that all MS patients have access to at least one visit per year, periodic access to neurologists is

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27 Bayer AG. “MS Diagnose: Die starke Antwort”. Available at: <http://www.ms-diagnose.ch/de/fruehdiagnose-und-diagnose/diagnoseverfahren-im-detail/index.php> [Accessed 06 October 2015].

28 Interview with French patient groups; interview with French neurologist.

29 Interview with English patient association.

30 “Access to treatments and services for people with MS in the UK” *Advances in Clinical Neuroscience and rehabilitation*, Supplement to ACNR Volume 12 Issue 2 MAY/JUNE 2012 ISSN 1473-9348.

31 Multiple Sclerosis International Federation (2013) “Atlas of MS”, available at <http://www.msif.org/wp-content/uploads/2014/09/Atlas-of-MS>. [Accessed 06 October 2015].

“a challenge”.<sup>32</sup> Availability of neurologists in Sweden varies significantly from region to region with access in rural areas around 10% of that in urban areas; however, there is capacity for cross-referral of neurologist consultations from one county to another. This issue is recognised in Sweden, and the national guideline on MS is seeking to address the number of neurologists in the future.<sup>33</sup>

- The Czech Republic is slowly losing highly trained medical professionals who move abroad due to difference in wages with other European Member States (e.g. Germany) where physicians can earn four times as much as in the Czech Republic. This is affecting the availability of neurologists,<sup>34</sup> and the Ministry of Health is currently implementing policies to increase the number of neurologists in the country.
- In Poland, the number of neurologists among doctors is relatively high but not all the neurologists have a contract with the social health insurance, or they may have a contract that limits the number of contracted visits. As a consequence, there are waiting lists for appointments with neurologists. There are also no dedicated outpatient clinics geared only toward treating MS patients, who continue to be put in the same group with all the other patients, the only differentiating factor being the treatment they receive.<sup>35</sup>

The number of neurologists was not a significant concern in the other 3 countries (Germany, Spain and France) although some concerns were expressed regarding the distribution of specialists, particularly in rural areas. In many countries, the number of specialists has been increasing. For example, in Germany, the number of neurologists has increased in the past 20 years following demands from the German medical association and the German Ethics Council, who had been calling for better diagnosis of brain related conditions. In 2015 there were approximately 4,800 neurologists (the second highest number of neurologists in Europe).<sup>36</sup> Equally in Spain and France, access to a neurologist has improved significantly over the last 10 years; however, respondents indicated that whilst access to specialised care in cities is not problematic, there are important geographical disparities and the speed of referral depends largely on where the patient lives.<sup>37</sup> Some patients in France have indicated that seeing a

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32 Interview with Swedish neurologist

33 Interview with Swedish patient association.

34 Interview with Czech Republic payer.

35 Interview with Polish policy expert.

36 Deutsche Gesellschaft für Neurologie. “Neuromedizinische Fachgesellschaften begrüßen die Stellungnahme des Deutschen Ethikrates zur Hirntoddiagnostik”. Available at: <http://www.dgn.org/presse/pressemitteilungen/3022-neuromedizinische-fachgesellschaften-begruessen-das-gutachten-des-deutschen-ethikrates-zur-hirntoddiagnostik> [Accessed on 06 October 2015].

37 Interview with Swedish patient association ; interview with French patient association – In France, the geographic disparities across regions range from 1.3 neurologists per 100,000 people to 0.5 neurologists per 100,000, which implies significant disparity of access to a consultation.

neurologist in some rural areas can take up to 6 months.<sup>38</sup> Spanish neurologists also indicated that access to neurologists needs to be improved in some regions.<sup>39</sup>

## 2.2. Diagnostic tools

In order to make the diagnosis, the neurologist will conduct a thorough neurological examination using simple methods, such as reflex testing, and a range of diagnostic tools (MRI, lumbar puncture, evoked potentials, blood tests, liver and renal function tests). In most countries, these are strictly defined by clinical guidelines (e.g. the 2014 NICE guidelines for MS in the UK<sup>40</sup>) and they largely follow the application of the 2010 McDonald criteria.

### *Access to MRI*

The time taken to receive the MRI varies significantly from country to country and is associated to a number of factors. In Spain, France, Germany, Czech Republic and Sweden, accessing an MRI scan is relatively rapid:

- **Spain:** accessing an MRI scan in Spain takes around 1 to 2 weeks; however, regional differences in access to MRIs could make this period longer.<sup>41</sup>
- **France:** accessing an MRI is not seen as problematic in France; indeed, the number of authorised MRI devices increased from 230 in 2003 to 646 in 2013.<sup>42</sup> Even so, there is evidence that the average waiting time has now increased slightly and stood at 37.7 days (5.3 weeks) in 2014.<sup>43</sup> Despite this, none of the respondents suggested that this was a hurdle in the diagnostic process.
- **Germany:** access to an MRI is good in Germany although the rapidity to access an MRI scan is perceived by some respondents as being contingent on a patient's health coverage. Respondents said that patients who hold public health insurance coverage

38 Le pays Briard – 13/02/2015 ; “Médecins spécialistes : une répartition inégale en Seine-et-Marne”. Available at: <http://www.lepaysbriard.fr/medecins-specialistes-une-repartition-inegalitaire-en-seine-et-marne-16708/> [Accessed on 06 October 2015].

39 Interview with Spanish neurologists

40 NICE. “Multiple sclerosis: management of multiple sclerosis in primary and secondary care NICE Guidance CG 186, section 1.2”. Available at: <http://www.nice.org.uk/guidance/cg186/chapter/Patientcentred-care> [Accessed on 06 October 2015].

41 Interview with Spanish neurologist.

42 Cemka Eval (2013) “Les Insuffisances en matiere d'equipements d'imagerie medicale en france: Etude sur les delais d'attente pour un rendezvous IRM en 2013”. Available at: [http://www.sfrnet.org/rc/org/sfrnet/htm/Article/2013/20130426-101458-362/src/htm\\_fullText/fr/2013-042%20ISA%20IRM%20Rapport%20v3-1.pdf](http://www.sfrnet.org/rc/org/sfrnet/htm/Article/2013/20130426-101458-362/src/htm_fullText/fr/2013-042%20ISA%20IRM%20Rapport%20v3-1.pdf) [Accessed on 06 October 2015].

43 Le Figaro (2014) “Les délais d'attente pour une IRM continuent d'exploser”. <http://www.lefigaro.fr/conjoncture/2014/07/08/20002-20140708ARTFIG00085-les-delais-d-attente-pour-une-irm-continuent-d-exploser.php> [Accessed on 06 October 2015].

(from a sick fund) face greater delays in access to MRIs than their counterparts with private health insurance (up to 2 months for the former, but only 2 weeks for the latter – although it was stressed that in urgent cases patients can have an MRI immediately). The disparity is due to the prioritisation of private insurance patients by physicians and hospitals given the greater financial reimbursements received from these patients. Despite this, according to the 2013 MS Atlas – an international survey on epidemiology and the availability of resources and services for people with MS which compares how support and healthcare services varies across countries – the average time delay to an MRI is 3.5 weeks, and Germany holds the third highest number of MRI machines (approximately 700) amongst EU countries.<sup>44</sup>

- **Czech Republic:** with good access to specialised MS centres, patients in the Czech Republic can receive an MRI scan in less than 4 weeks and a lumbar puncture within a week after that.

However, respondents indicated that in Sweden, the UK and Poland, referral and access to an MRI scan remains challenging and adds another hurdle to the process.

- **Sweden:** in Sweden, as in many other countries, patients can experience significant waiting times for MRI scans. MRIs are operated on a first-come-first-served basis, and MS patients are not prioritised for MRIs. The queue for an MRI can be as short as 4 weeks or as long as 3 months, depending on the availability of MRI machines. The delay to access is generally shorter if a patient is referred to an MS centre. In addition, delays can be shortened (to approximately 4 weeks) if public hospitals purchase help from private providers. We heard that in particular areas in Sweden, access to an MRI can be achieved in 1 week. However, figures from the MS Atlas indicated that the approximate time (weeks) from initial contact with health system to access to an MRI can go up to 12 weeks (4 months) – see Figure 3 below.
- **UK:** delay in referral for an MRI is the main barrier to early diagnosis in the UK. The National Health Service (NHS) recommends no one should wait longer than 6 weeks for a diagnostic test. Referrals are commonly made by the neurologist (although it is possible to get a referral for MRI from the PCP). Stakeholders estimated the waiting time for an MRI as 4 weeks to 6 months, citing the perceived cost of an MRI scan and the lack of prioritisation for MS patients as negatively impacting the overall waiting time. This is consistent with studies showing that the UK has only 6.8 MRI units per million people, far fewer than the European average of 10.5,<sup>45</sup> and reports that almost 17,000

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44 Deutsche Gesellschaft für Neurologie. (2015) "Neuromedizinische Fachgesellschaften begrüßen die Stellungnahme des Deutschen Ethikrates zur Hirntoddiagnostik". Available at: <http://www.dgn.org/presse/pressemitteilungen/3022-neuromedizinische-fachgesellschaften-begrueessen-das-gutachten-des-deutschen-ethikrates-zur-hirntoddiagnostik> [Accessed on 06 October 2015].

45 OECD (2014) Health at a Glance: Europe 2014 – OECD Indicators, accessible at [http://ec.europa.eu/health/reports/docs/health\\_glance\\_2014\\_en.pdf](http://ec.europa.eu/health/reports/docs/health_glance_2014_en.pdf)

patients waited longer than the target time in April 2014 – more than double the total in the same month the previous year and the highest for 6 years.<sup>46</sup>

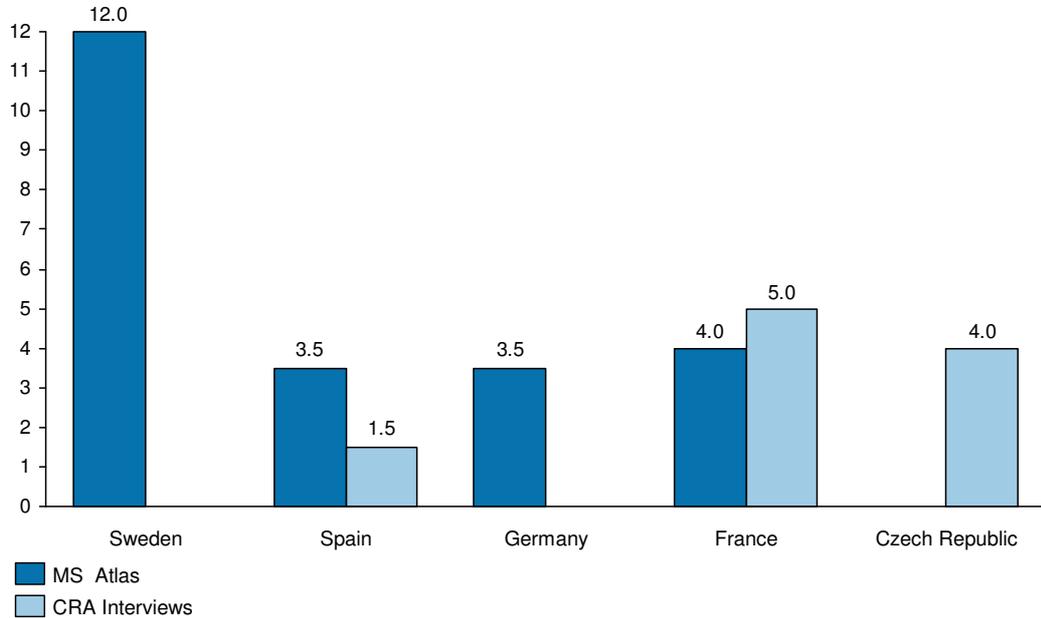
- **Poland:** respondents in Poland indicated that accessing an MRI is an important hurdle in the diagnostic process, especially in the outpatient setting. Despite having good access to MRI machines and other advanced imaging diagnostic tools, access varies widely depending on the care setting. In a specialised hospital setting, a patient can be admitted for an MRI in as little as 1 day. However, in less specialised hospitals or clinics, referral for an “urgent” MRI scan in the outpatient setting can take about 6 months to a year, mainly due to the limited number of examinations contracted with the local branches of the health insurance fund. Poland has poor distribution of MRIs across the country, and MRI referral is the main hurdle, largely because neurologists are the only healthcare professionals (HCPs) able to prescribe MRIs, and access to neurologists is poor.<sup>47</sup> All specialists can direct patients for an MRI. It should be underlined that GPs cannot prescribe MRIs, but due to poor access to neurologists, waiting time for an examination is long. Once a patient gets access to a hospital or a neurologist, there are fewer hurdles to diagnosis. In the inpatient setting, waiting times are just a day, as there are no restrictions to the use of various diagnostic tools.

The interviews are somewhat consistent with existing data from MS Atlas and show that there is significant variation across countries. Poland, the UK and to a lesser extent Sweden appear to have the longest delay – up to 6 months – whereas France, Germany, Spain and the Czech Republic provide rapid access to MRI scans.

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46 Daily Mail – 27 June 2014: Deadly shortage of cancer scanners that shames UK: Britain has fewer MRI machines than almost any other Western country; <http://www.dailymail.co.uk/news/article-2672902/Deadly-shortage-cancer-scanners-shames-UK-Britain-fewer-MRI-machines-Western-country.html#ixzz3odAIZONd>

47 Interview with Polish KOL neurologist. September 2015.

**Figure 3: The approximate time (weeks) from initial contact with medical system to MRI**

Source: MS Atlas 2013 Note: No information identified for Czech Republic, Poland, the UK.

### 2.3. Implications and good practices

In this chapter we have explored the wider diagnostic process and examined barriers to rapid diagnosis. We find this varies significantly between countries and even between different patient populations (urban and rural, for example) in the same country. According to respondents, the main barriers include the following:

1. Delays in referral of patients with suspected MS to a neurologist/MS centre due to
  - lack of awareness of MS Symptoms and insufficient training (Poland, Czech Republic, Sweden and the UK)
  - a culture of “watching and waiting” which creates reluctance to refer patients to a neurologist (UK, Poland).
2. A limited number of neurologists (UK, Sweden, Czech Republic) or limited access to a neurologist (Poland).
3. Significant variation in the time taken to receive the MRI (especially in Poland, the UK and to some extent Sweden). This varies from country to country and is associated with a number of factors including the cost of MRI and the distribution of MRI scanners across the country.

The diagnosis and referral process for a typical patient was not seen as a significant barrier in Germany, France, Spain, Sweden or the Czech Republic. Respondents indicated that the average time to receive a diagnosis was acceptable and the delay in diagnosis was not necessarily a significant barrier (although many patients note that this could vary significantly

by region).<sup>48</sup> Even so, it can still take weeks, months, and sometimes even years for a diagnosis to become clear.<sup>49</sup> Specifically, as a 2013 study based on the data of the German MS registry found, the time to diagnosis is approximately 3 years in Germany.<sup>50</sup> Our survey found that the average time to diagnosis in Germany is 1 year. Even in countries with rapid diagnosis, significant variations exist from region to region. In France, the overall diagnostic process takes no more than 1.5-2 months, sometimes 3 months; whilst in Spain, the time from going to a PCP to seeing a neurologist may be 3 months, and a full diagnosis may take up to a year.<sup>51</sup> However, the MS Atlas suggests that the approximate time from initial contact with the medical system to diagnosis is between 1 and 3.5 weeks in Spain which is significantly lower than our survey suggests.<sup>52</sup>

In the Czech Republic and Sweden, although patients with access to MS centres are diagnosed quickly – in 1 to 6 months – this is not the case for all patients. It can take up to 4 years to receive a diagnosis in some regions if PCPs do not diagnose symptoms effectively and quickly. Similarly, in Sweden, the estimated time to diagnosis, according to interviewed respondents, can be as long as 5-6 months. However, respondents acknowledged that patients with severe symptoms are diagnosed much faster, typically within a few weeks.

In the UK and in Poland, the delay in diagnosis was perceived as problematic by healthcare professionals and thought to be driven by lack of access to specialised neurologists, poor access to MRIs, and slow referral by PCPs. In Poland, respondents indicated that the mean time from first symptoms to diagnosis is 2.6 years, depending on when a patient presents in the physician's office.<sup>53</sup> One reason for this is that the first presentation of symptoms, especially when mild, is often ignored and the diagnosis process is often begun after the second relapse, which triggers the diagnosis.

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48 Interview with: Swedish patient association, French patient association, Spain KOL neurologist/policy experts, German KOL and patient association.

49 Interview with German patient association.

50 Hoer. A., Schiffhorst, G., Zimmerman, A., Fischaleck, J., Gehrmann, L., Ahrens H., Gunther, C., Sigel, K-O., Osowski U., Klein, M., and Bleb, H-H. (2014) "Multiple sclerosis in Germany: data analysis of administrative prevalence and healthcare delivery in the statutory health system". Available at: <http://www.biomedcentral.com/1472-6963/14/381> [Accessed on 06 October 2015].

51 Interview with Spanish neurologist; interview with Spanish physiotherapist.

52 MS International Federation (2013) "Atlas of MS". Accessible at <http://www.msif.org/about-us/advocacy/atlas/>

53 BBC (2013). "Multiple sclerosis patients are missing out on drugs". Available at: <http://www.bbc.com/news/health-22307916> [Accessed on 06 October 2015].

**Table 11: Reported overall length of diagnosis in selected countries**

	Germany	France	Spain	UK	Czech R	Sweden	Poland
<b>Min</b>	2 weeks	1 week	-	1 week	1 month	3 months	-
<b>Max</b>	-	3 months	1 year	6 years	4 years	3 years	-
<b>Avg</b>	1 year	4 weeks	3 months	6 months	6 months	5-6 months	2.6 years

In addition to significant differences between countries, the interviews highlighted some policy actions that may accelerate the diagnosis and referral process.

- MS educational component in PCP training:** In Germany and France, although PCPs and neurologists share responsibility for diagnosing MS patients, the final diagnosis and initial therapy initiation must always be made by a neurologist. (PCPs also follow up the patient's medical care and write ongoing prescriptions.) Stakeholder groups in both of these countries indicated that delays to referral are minimal as PCPs are generally more aware of MS today than in the past thanks to the MS educational component(s) in their medical training as well as training programmes organised by MS networks.
- Greater access to neurologists, and investment in MRI in rural areas:** In France, Germany and Sweden, respondents did not perceive the lack of neurologists although regional difference exists and access remains a problem in rural areas. In all of these markets, significant investments have been made in developing and maintaining the specialists and healthcare infrastructure. Particularly, investment in MRIs means these are largely available in France, Spain and Germany, even though some delays can occur in accessing them at a regional level.

### 3. The initiation of treatment and clinical management

Following diagnosis, there are a range of factors that contribute to the decision to initiate treatment – such as treatment guidelines, eligibility criteria for access to medicines, and the extent to which there is access to innovative treatments.

According to the EMSP Code of Good Practice, patients should have “timely access to appropriate drugs (as defined by scientific research)”. Whilst EMSP has not strictly defined what this means in terms of types of treatment, some countries have defined this in their treatment guidelines. In order to look at this, we discussed with respondents the speed with which treatment was initiated; the types of products used, particularly distinguishing symptomatic treatment from disease-modifying drugs<sup>54</sup> and more recently introduced medicines such as Teriflunomide (Aubagio), dimethyl fumarate (Tecfidera) and Alemtuzumab (Lemtrada); and the types of patients who had access to these medicines.

Although not included in the EMSP guidelines, we also consider differences in off-label use and how these affect treatment options for some patients.

#### 3.1. Initiation of treatment

As described in the last chapter, the diagnosis is usually realised by a neurologist, and in most cases, only he can prescribe disease modifying drugs.<sup>55</sup> Whilst this is a strict requirement in most countries, Germany is an exception to the rule: the PCP can prescribe DMDs for ongoing treatment, although this task is generally left to the neurologist.

##### *Restrictions on initiation*

In Germany, France and Spain, neurologists are permitted to decide what DMDs to prescribe to patients and are allowed to treat all types of MS with DMDs, with few limits to reimbursement albeit some administrative procedures.<sup>56</sup> For example, once diagnosed, RRMS patients in Germany can access DMD treatment with very little delay, although some respondents noted that some physicians are wary of treating patients at the first exacerbation. In Spain and in France, the neurologist is free to initiate treatment, although in the case of some high cost treatment (some DMDs), the neurologist must systematically file a prior-authorisation with the insurance company in order to confirm the reimbursement.<sup>57</sup> In France, this procedure to benefit from social security coverage can take time, and delays vary greatly by region (less

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54 Disease-modifying drugs (DMD) include interferon beta (Betaferon, Avonex, Rebif, Extavia), glatiramer acetate (Copaxone), natalizumab (Tysabri) and fingolimod (Gilenya).

55 Universitätsmedizin Göttingen. “Multiple Sklerose”. Available at: <http://www.neurologie.uni-goettingen.de/index.php/multiple-sklerose.html> [Accessed on 06 October 2015].

56 Interviews with French, German and Spanish neurologists.

57 Interview with Spanish neurologist.

than 2 weeks in Paris versus several weeks in other regions)<sup>58</sup>. This procedure must be renewed every 5 years.

In Sweden, it is up to the clinic to decide which medication should be given, as appropriate for each patient.<sup>59</sup> This means that different regions have different rules on reimbursement, so one region may be more generous with innovative treatment than another.

In the UK, consultant neurologists are free to prescribe all DMDs that have been approved for use by the NHS. The availability of each drug may vary between England, Scotland, Wales and Northern Ireland, and the choice of medicine is heavily influenced by local clinical guidelines; however, these guidelines are not statutory and are not linked to reimbursement restrictions, so clinicians remain free to prescribe as they find fitting, in accordance with the treatment label. Most DMDs go through an appraisal by a health technology assessment (HTA) agency – the National Institute for Health and Care Excellence (NICE) in England or the Scottish Medicines Consortium (SMC) in Scotland. NICE can approve the use of a product for a patient population that is more limited than the licensed population. One example of this is dimethyl fumarate, which is approved by the European Medicines Agency (EMA) for the treatment of adult patients with relapsing remitting multiple sclerosis.<sup>60</sup> However, NICE's technology appraisal guidance for dimethyl fumarate only recommends it as a possible treatment for people with active RRMS that isn't highly active or rapidly evolving severe relapsing remitting (RES) MS.<sup>61</sup>

Poland and Czech Republic have introduced eligibility conditions and other limitations on access to treatment, described below:

- Poland has introduced some restrictions on the eligibility criteria for patients to access the DMD drug programme, and also on the number of MS patients eligible to receive DMD treatment (due to contract value restrictions) and the number of medical centres entitled to use DMDs (only 34 of 118 centres treating with first-line DMDs can also prescribe second-line DMDs). A hospital specialising in neurology is only allowed to treat a certain number of patients per year. This varies across regions in Poland. For example, treatment is most easily available in Warsaw and Łódź; but there are 100 people waiting to be treated in the Pomorskie region.<sup>62</sup>

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58 Interview with French patient association.

59 Interview with Swedish Patient association.

60 European Medicines Agency (2014) Tecfidera: EPAR – European Medicines Agency; accessible at [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/EPAR\\_-\\_Product\\_Information/human/002601/WC500162069.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002601/WC500162069.pdf)

61 National Institute for Health and Care excellence – August 2014; NICE technology appraisal guidance [TA320]; Dimethyl fumarate for treating relapsing-remitting multiple sclerosis accessible at: <https://www.nice.org.uk/guidance/ta320>

62 Interview with Polish neurologist.

In addition, patients must meet certain criteria in order to qualify for reimbursement of DMDs. This is done through a point scoring system, based on duration of the disease, number of relapses in the last year, and Expanded Disability Status Scale (EDSS) score. A number of criteria have been introduced which exclude patients from beta-interferon (e.g. sensitivity to interferon beta, primary or secondary progressive forms of the disease, decompensated liver failure, thyroid problems, untreatable depression, uncontrolled depression, anaemia, or pregnancy). Other similar exclusion criteria have been developed for glatiramer acetate.<sup>63</sup> In addition, in the second-line drug programme, the inclusion criteria are narrower than in the label (e.g. natalizumab and fingolimod).

- In the Czech Republic, MS patients can only have access to treatment and be prescribed DMDs within a specialised MS treatment centre. According to national guidelines, the waiting list to start treatment should not be longer than 1 month. If the treatment centre is unable to initiate treatment within the first month, the patient is advised to go to another centre where there are more resources.<sup>64</sup> However, in practice, patients generally wait 2 to 3 months to receive treatment. Similar to the conditions applied in Poland, patients can be treated after only one relapse or one instance of active RRMS, which in practice means having RRMS diagnosed and at least one relapse or Gd+ in the preceding 12 months. However, criteria for second-line treatments require patients to have 2 relapses within 1 year. Some patients must wait a long time to meet this criterion, during which they do not receive treatment. Patient groups are currently working to lower the treatment criteria so that more patients can receive earlier access to effective treatments.
- In the UK and in Sweden, there are clinical guidelines that provide clear and comprehensive recommendations on DMD initiation and monitoring.<sup>65</sup> In the UK, the Association of British Neurologists (ABN) guidelines provide a consensus on the best use of DMDs to treat MS.<sup>66</sup> There are currently eight DMDs licensed in the UK, and physicians are recommended to prescribe these as they see fit.<sup>67</sup> Funding for DMDs comes directly from NHS England, which reduces the potential for further restrictions at regional level.<sup>68</sup> According to ABN guidelines, treatment is initiated for patients over

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63 Polskie Towarzystwo Stwardnienia Rozsianego (2015) "Leczenie Stwardnienia Rozsianego (ICD-10 G 35)". Available at: [http://www.ptsr.org.pl/dane/files/Leki/zalacznik\\_b29\\_2015-05.pdf](http://www.ptsr.org.pl/dane/files/Leki/zalacznik_b29_2015-05.pdf) [Accessed 06 October 2015].

64 Interview with Czech Republic payer

65 Interview with KOL neurologists in Sweden and the UK

66 Scolding, N et al. (2015). Association of British Neurologists: revised (2015) guidelines for prescribing disease-modifying treatments in multiple sclerosis. *Practical neurology, practneurol-2015*.

67 These are :Avonex (beta interferon-1a); Rebif (beta interferon-1a); Betaferon (beta interferon -1b); Extavia (beta interferon- 1b), Copaxone (glatiramer acetate); Tysabri (natalizumab); Gilenya (fingolimod); Tecifdera (dimethyl fumarate)

68 Interview with UK patient association.

the age of 18 with active MS (2 clinically significant relapses in the previous 2 years), relapsing onset.<sup>69</sup> This was further confirmed by respondents who noted that DMDs are only given to patients with RRMS, with a clinically isolated syndrome (CIS), or with the first phase of secondary progressive MS (SPMS). In Sweden, DMDs are initiated according to local guidelines.<sup>70</sup> However, it was suggested that neurologists can prescribe outside these guidelines if there is sufficient supporting clinical evidence for use (for example, the use of rituximab for MS).

**Figure 4: Conditions and other limitations on access to treatment**

Countries	Restrictions / Conditions
<b>Czech Republic</b>	<p>Treatment only available within specialised MS treatment centre.</p> <p>Two attacks in the last year or 3 attacks in the last 2 years, and with an EDSS score of 4.5 or less.</p> <p>Approval is required if treatment is to be continued for more than 4 years, and treatment should be stopped if the patient experiences 2 or more severe relapses a year, has a 1 point increase in the EDSS score in a year, or loses the ability to walk.<sup>71</sup></p>
<b>France</b>	<p>No formal restrictions/conditions – however, prescribers must systematically file a prior-authorisation to insurance companies in order to obtain the patient’s long-term disease reimbursement status (ALD), which ensures full social security coverage.</p> <p>Patients are also unable to bulk order their DMDs to cover several months of treatment and must physical retrieve medicines in pharmacies or hospitals on a monthly basis.</p>
<b>Germany</b>	No restrictions/conditions.
<b>Poland</b>	<p>Indirect restrictions on the number of patients with MS eligible to receive DMD treatment due to value of national health fund contract to hospital limitation.</p> <p>Limited number of medical centres entitled to use second-line DMDs (only 34) vs 118 centres treating with first-line DMDs.</p>

69 Scolding, N., et al (2015). Association of British Neurologists: revised (2015) guidelines for prescribing disease-modifying treatments in multiple sclerosis. Practical neurology, practneurol-2015.

70 Svenska MS-sällskapet. "Metodboken". Available at: <http://www.mssallskapet.se/Metodboken.html> [Accessed on 6 October 2015].

71 Lecich website, available at <http://www.olecich.cz/modules/medication/detail.php?code=0026252&tab=prices> [Accessed on 6 January 2014].

	Patients must meet certain criteria in order to qualify for reimbursement of DMDs – point system is based on the duration of the disease, number of relapses in the last year, and the Expanded Disability Status Scale (EDSS) score and another set of criteria for second-line products.
<b>Spain</b>	No restrictions/conditions – prescribers must occasionally file a prior-authorisation to insurance companies in order to confirm the reimbursement for high cost drugs.
<b>Sweden</b>	Beta-interferons or glatiramer acetate should be initiated in patients diagnosed with RRMS according to the 2010 revised McDonald criteria, or if there is suspected MS onset where the MRI shows at least two T2 lesions that are at least 3 millimetres in size. <sup>72</sup>
<b>United Kingdom</b>	Eligible patients will normally be ambulant (maximum EDSS 6.5). Active MS (2 clinically significant relapses in the previous 2 years), relapsing onset. i.e. only patients with RRMS, CIS, or the first phase of SPMS. <sup>73</sup>

Source: CRA analysis

#### *Off-label use for progressive forms of MS*

One factor affecting initiation is the policy on off-label use. For patients with progressive forms of MS, e.g. Primary Progressive MS (PPMS) and Progressive Relapsing MS (PRMS), some medicines are prescribed off-label as there is a lack of suitable treatment options. Equally, in the case of children, some therapies have not been formally evaluated by clinical trials in children.

It is widely acknowledged across all countries that the evidence shows existing treatment to be ineffective for “inactive” SPMS (no more attacks) and PPMS patients. Currently, no DMDs are indicated for these conditions, which leaves very limited options for these types of patients.

Poland, the Czech Republic and the UK have taken a very strict approach that there are no DMD options for SPMS patients. For example, in the Czech Republic, physicians are not allowed to prescribe drugs off-label, since these will not be approved for reimbursement. If the hospital dispenses a DMD off-label, it will not be reimbursed and the hospital will be responsible for covering the costs. Although this was not always an issue, insurance companies have become more attentive about checking patient files to see if the appropriate conditions for treatments are met.

<sup>72</sup> Swedish MS Society (2013) “Recommendations for treatment with interferon and glatiramer acetate in MS”, available at <http://www.mssallskapet.se/Lakemedel.html>, accessed January 6, 2014.

<sup>73</sup> Scolding, N., et al. (2015). Association of British Neurologists: revised (2015) guidelines for prescribing disease-modifying treatments in multiple sclerosis. Practical neurology, practneurol-2015.

In France, Germany and Sweden, however, other treatments such as azathioprine (Imurel), mitoxantrone (Elsep), cyclophosphamide (Endoxan), and mycophenolate mofetil (Cellcept) are considered if existing DMDs have proven unsuccessful. Some patients are put on experimental treatments, to be more aggressive (mitoxantrone and Endoxan). In Sweden and France, Mabthera (rituximab) is widely used off-label to treat difficult cases of multiple sclerosis such as PPMS and SPMS, for which there are currently no treatment options available with a marketing authorisation<sup>74</sup> (in Sweden this has resulted in 1,800 patients being treated<sup>75</sup>).

Regarding paediatric treatment, in most countries regulatory approval restricts the administration of MS disease-modifying therapies to patients 12 years and older. However, according to interviews, Poland represents an exception, where first-line treatments are reimbursed without age reimbursement restriction,<sup>76</sup> although this does require formal/written consent by parents of younger patients.

### *Symptomatic treatment*

MS patients are often affected by a range of symptoms caused by neurologic injury resulting from the disease. Common symptoms include weakness, ambulatory impairment, sensory disturbances that may be unpleasant or even painful, ataxia and tremor, bladder and bowel dysfunction, sexual dysfunction, fatigue, spasticity, vertigo, depression and other psychiatric symptoms, cognitive impairment, and paroxysmal symptoms such as cramps, spasms, Lhermitte's sign, and Uhthoff's phenomenon.<sup>77</sup> Neurologic care of people with MS often involves a greater degree of management of the symptoms caused by MS than appropriate prescription of disease-modifying treatments.

In Germany, France and Spain, patients can have access to symptomatic treatment before being formally diagnosed with MS. In Germany, such symptomatic care is often provided at rehabilitation centres; however, access to these centres is often limited to patients who can demonstrate active medical symptoms. Thus, the Deutsche Multiple Sklerose Gesellschaft (DMSG – patient association) is active in advocating for patients to receive increased access to non-pharmacological treatment from health insurances.

There are also multiple symptomatic treatments available on the NHS in the UK. However, eligibility for these treatments differs widely across regions.

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74 Hauser, S. L. et al. (2008). "B-cell depletion with rituximab in relapsing–remitting multiple sclerosis". *New England Journal of Medicine*, 358(7), 676-688.

75 [https://vap.carmona.se/open/msvap/graf/antal\\_reg/](https://vap.carmona.se/open/msvap/graf/antal_reg/)

76 EMSP (2015) "Defeating MS Together". The European Code of Good Practice in MS.

77 Markowitz, C. (2010). Symptomatic therapy of multiple sclerosis. *CONTINUUM: Lifelong Learning in Neurology*, 16(5), Multiple Sclerosis), 90-104.

In the United Kingdom, the term “postcode lottery”<sup>78</sup> refers to differences in access to health treatment throughout the country, meaning that where you live (i.e. your postcode) can define the quality and availability of national health services you can expect. Patients indicated that this type of “postcode lottery” exists for symptomatic therapies, including treatment for spasticity, pain and incontinence. On the whole, stakeholders felt that symptomatic treatment could be prescribed more frequently.<sup>79</sup>

In the Czech Republic, patients are advised to seek out symptomatic treatment from specialists. In general, spasticity is treated with baclofen, pain and seizures are treated with carbamazepine and gabapentin, and tremors are treated with clonazepam.

In Poland, interferons and other immunotherapies were only introduced in the middle of the 2000s largely due to their budget impact,<sup>80</sup> and as a result, standard MS treatment in Poland relies as much on DMDs as on glycocorticosteroids, symptomatic treatment, and rehab during acute attacks of the disease. According to the EMSP, 90% of MS patients receive symptomatic treatments but only a small percentage have access to rehabilitation centres.<sup>81</sup>

In general, there is high usage of complementary alternative treatments amongst MS patients across all countries. Symptomatic treatments are more widely available than DMDs and are often the only pharmaceutical treatments available to patients.

### 3.2. Access to innovative therapies

Access to innovative therapies varies widely across countries. Based on the interviews, we find that Sweden, France, and the UK provide reasonably good access to new treatments. The most recent evidence on this remains the 2014 CRA MS access report, in which we observed that the Scandinavian countries provide better access to innovative second-line treatments than the rest of Europe. As illustrated in Figure 5, in Norway, 39% of MS treatment are innovative second-line treatments, 31.8% of prescriptions in Sweden, and 29.5% in Denmark. In Eastern European countries, this ratio is significantly lower.

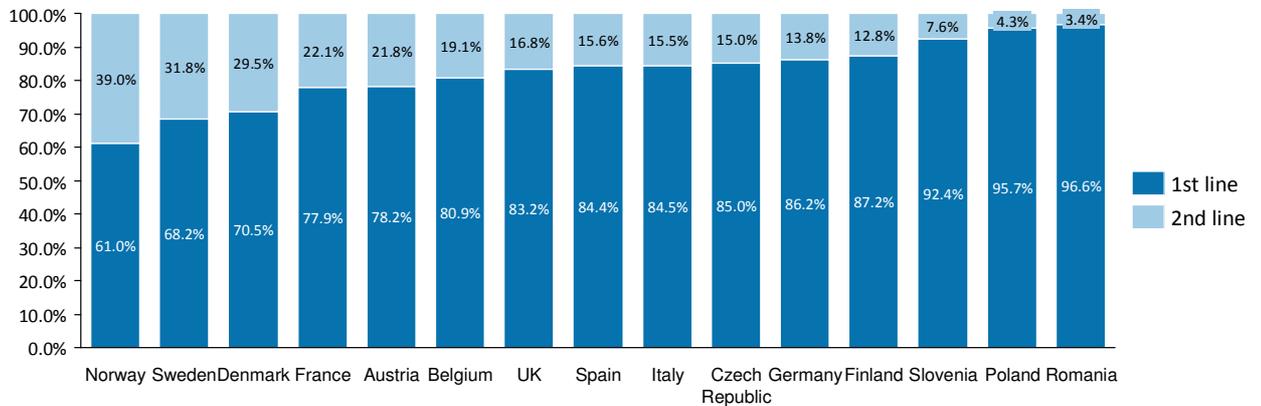
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78 In the United Kingdom, the term “postcode lottery” refers to the way the allocation of postcodes can affect the services available to the people who live within them. The term is also used to refer to the way local budgets and decision-making can lead to different levels of public services in different places especially with regard to health and social services, e.g. access to cancer drugs or quality of education.

79 Interview with patients’ associations in the UK.

80 Matschay, Arleta et al. (2008). “Cost analysis of therapy for patients with multiple sclerosis in Poland”. [http://www.if-pan.krakow.pl/pjp/pdf/2008/5\\_632.pdf](http://www.if-pan.krakow.pl/pjp/pdf/2008/5_632.pdf)

81 EMSP (2015) “Multiple sclerosis in Europe”, accessible at <http://www.emsp.org/wp-content/uploads/2015/08/MS-in-EU-access.pdf>

**Figure 5: Proportion of all MS patients receiving innovative treatments (%)**

Source: CRA analysis using IMS 2013 (Austria, Belgium, Denmark, Finland, Germany, Italy, Poland, Spain, Sweden), GERS (France), Farmastat (Norway), MS National Programme (Romania), CEE average (Slovenia)

In Germany, all DMD treatments approved by the EMA or the Federal Institute for Drugs and Medical Devices (BfArM) can be used without restriction and new treatments are quickly accessible. In 2009, interferon-beta and glatiramer acetate were the most prescribed DMDs (58.66% and 26.85% of all prescriptions respectively).<sup>82</sup>

Most of the newer MS treatments are available in France (or going through the reimbursement process). Dalfampridine has been on the market since April 2013. Dimethyl fumarate was only approved for reimbursement in June 2014, more than 15 months after EMA approval, and alemtuzumab is not yet on the market. The French Ministry of Health authorised the prescription of nabiximols in January 2014, the first treatment specifically designed for patients with MS-related spasticity, although the treatment is not yet available as it is still in the price negotiation process.<sup>83</sup>

In the Czech Republic, there are limits on the types of medications MS patients have access to. Hospitals restrict access to expensive treatments like dimethyl fumarate and alemtuzumab. Fampridine is not reimbursed. Possible treatments available in the Czech Republic include interferon beta, or glatiramer acetate, intravenous immunoglobulins, and azathioprine. The reimbursement process can delay access to some treatments. For products that demonstrate sufficient benefits, a temporary reimbursement pathway has been introduced which grants access to new therapies for a period of 2 years (with a prolongation of 1 year). The product

<sup>82</sup> Hapfelmeier, A., Dippel F.W., Schinzel, S., Holz, B., Seiffert, A. and Maurer, M. (2014) "Aktuelle Aspekte zur Versorgungssituation und zu den Behandlungskosten bei Patienten mit Multipler Sklerose in Deutschland". Available at: <https://www.thieme-connect.com/products/ejournals/abstract/10.1055/s-0033-1335883> [Accessed on 06 October 2015].

<sup>83</sup> Clavreul, L., and Hecketsweiler, C. (2014) "Le Sativex, médicament à base de cannabis, autorisé en France". Available at: [http://www.lemonde.fr/sante/article/2014/01/09/le-sativex-medicament-a-base-de-cannabis-autorise-en-france\\_4344958\\_1651302.html](http://www.lemonde.fr/sante/article/2014/01/09/le-sativex-medicament-a-base-de-cannabis-autorise-en-france_4344958_1651302.html) [Accessed on 06 October 2015].

must have been reimbursed in at least two other countries similar to the Czech Republic.<sup>84</sup> However, many patients (over 2000) currently have access to innovative therapies through clinical trials.

In the UK, patients get access to the latest innovative therapies, with some exceptions. However, this varies from regionally across the UK. In England and Wales, the evaluation of new drugs is conducted by NICE, and upon favourable recommendation a drug must be available for prescription within 90 days.<sup>85</sup> In Scotland, reimbursement of medicines is conducted by the Scottish Medicines Consortium (SMC), which conducts its own evaluation. In 2014, the NICE MS Clinical Guideline 186 did not recommend fampridine – which is approved in Europe for MS patients who have severe walking disability – for use on the NHS in England and Wales due to its poor cost/benefit ratio.<sup>86</sup> SMC also denied the use of the drug in Scotland. Similarly, both NICE and the SMC rejected the drug nabiximols (prescribed for the treatment for MS-related spasticity) in their draft clinical guidelines for MS, but the All Wales Medicines Strategy Group (AWMSG) overruled the NICE guideline in Wales and approved access to the treatment, meaning Wales will become the only place in the UK where people with MS can routinely access the medicine on the NHS.<sup>87</sup>

In Poland, only older DMDs are reimbursed, such as interferon beta-1b, glatiramer acetate, fingolimod and natalizumab. There is currently no reimbursement of newer innovative products such as dimethyl fumarate, teriflunomide, alemtuzumab, newer peginterferon beta-1a, or of symptomatic treatments like fampridine and nabiximols.

### 3.2.1. Timeliness

In addition to restrictions imposed on the coverage, we also look at the average time between marketing authorisation and patient access to innovative medicines, and the extent to which the HTA and reimbursement process can have an impact on the time patients must wait to have access to the treatment. Whilst Germany and Sweden are systematically among the first countries to gain access to innovative medicines, other countries vary in their approval timeline.

Theoretically, Germany and the UK have no reimbursement delays after EMA approval. However, in practice, drug uptake in the UK may be delayed until the relevant cost effectiveness analysis by NICE/SMC is carried out. For example, in the UK, the NICE appraisal

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84 Law Office Mareckova. "Pharmaceuticals in the Czech Republic". Available at: <http://www.pharmaceuticals-czech.com/prices-and-reimbursement> [Accessed on 06 October 2015].

85 <https://www.nice.org.uk/news/press-and-media/nice-issues-good-practice-guidance-for-local-formularies>

86 NICE (2014) "Multiple sclerosis in adults: management", clinical guideline. Published: 8 October 2014. [nice.org.uk/guidance/cg186](http://nice.org.uk/guidance/cg186)

87 <https://www.mssociety.org.uk/ms-news/2014/08/sativex-update-welsh-minister-says-yes>

initially rejected fingolimod, ultimately recommending it only once there was a patient access scheme (PAS) and the product was made available to patients.<sup>88</sup>

In Germany, rapid access to treatment can be explained by nature of the pricing-and-reimbursement regime, which allows free pricing upon market launch when the HTA review is completed. The AMNOG legislation requires a mandatory benefit assessment, with the subsequent price negotiation process for new medicines to be completed within 1 year of product launch. This allows the product to be launched and reimbursed although the free pricing is now limited to a maximum of 12 months after launch.<sup>89</sup>

France experiences substantial delays due to formal reimbursement procedures. However, in France, DMDs for MS benefit from an early access programme known as an ATU (“Autorisations Temporaires d’Utilisation”) or Temporary Authorisations for Use, which enables patient access to medicinal products that have not yet been granted a Marketing Authorisation (MA) or the full reimbursement process. The aim of ATUs is to provide early access to new, promising treatments where a genuine public health need exists, i.e. in the treatment of patients suffering from serious diseases such as MS and having reached a situation of therapeutic impasse. Some new MS treatments (alemtuzumab, dimethyl fumarate) benefit from a “cohort ATU” which applies to a drug that is presumed safe and effective, having reached an advanced stage of development. This is intended to accelerate patient access to treatment for diseases with high unmet medical needs as part of precisely defined criteria in the protocol for therapeutic use developed by the ATU holder laboratory in collaboration with the French National Agency for Medicines and Health Products Safety (ANSM).

In most other countries, decisions about the price of drugs paid by the healthcare systems must be made before the drug is launched in the market, which can create significant delays in access. This is the case in Poland, where administrative reimbursement procedures with the Ministry of Health along with procurement processes such as the tender procedure by the National Health Fund, the NFZ can often take several months, which translates into access delays.<sup>90</sup> According to the Polish “Reimbursement Act”, all reimbursement process (from application to the final decision) should take approximately 180 working days, much of the access delay can be attributed to price negotiations, which conclude the reimbursement process.

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88 The draft recommendation was published in August 2011. After Novartis submitted a proposed PAS, NICE still did not recommend it in the second draft recommendation, published in December 2011. Novartis revised its analyses for a subgroup of the licensed population, so fingolimod is now recommended for this subgroup, i.e. “adults with highly active RRMS, whose relapses have increased or stayed the same compared to the previous year, despite them taking beta interferons”. See the NICE 2012 fingolimod commentary for details around the recommendation history.

89 Ruof, J., Schwartz, F. W., Schulenburg, J. M., & Dintsios, C. M. (2014) „Early benefit assessment (EBA) in Germany: analysing decisions 18 months after introducing the new AMNOG legislation”. *European Journal of Health Economics*, 15(6), 577-589.

90 Interview with payer advisor 2

### 3.2.2. Duration of therapy

According to the EMSP Consensus Paper II, “it is recommended to continue immunomodulatory therapy with regular neurological follow-up examinations, if a therapeutic effect still appears plausible (e.g. clearly reduced number of relapses and relapse severity compared to the pre-therapeutic phase, reduced disease progression) and no severe side effects reduce the patient's quality of life”.<sup>91</sup>

Most countries appear to be consistent with this practice; however, one country, Poland, has introduced temporal restrictions on the use of DMDs. The government started a drug programme for second-line DMDs in 2013 whereby patients could be treated with a DMD for a maximum of 5 years.<sup>92</sup> After 5 years, the treatment “spot” is transferred to the next person on the treatment waiting list.<sup>93</sup> The Minister of Health recently removed the 5-year restriction for first-line therapy, but temporal constraints remain for more costly second-line treatment.<sup>94</sup> Around this time, Poland also enabled the automatic transfer of young patients to adult clinics after they turn 18, and started reimbursing therapy for first-line patients under 12 years (with parental consent), and guaranteed the resumption of treatment for pregnant women after their delivery.

### 3.2.3. Flexibility of treatment

The EMSP Code of Good Practice in MS indicates that “because MS is unpredictable, particularly with regard to relapse occurrence and speed of disability progression, a service must have the capacity to respond in a timely manner without excessive delay and bureaucracy”.<sup>95</sup> Consequently, this section looks at the extent to which treatment is provided flexibly, taking into account heterogeneity of the disease (with disease progression varying depending on age of onset, apparent disease severity). This includes the extent to which guidelines are followed, the role of patient choice, and the flexibility for exploring other treatment options.

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91 EMSP (2008) “Consensus Paper II: Basic and escalating immunomodulatory treatments in Multiple Sclerosis”.

92 EMSP, “Parliamentary event in Poland: ‘The faces of MS’”, available at <http://www.emsp.org/news-messages/parliamentary-event-in-poland-the-faces-of-ms/> Accessed 7 January 7 2014; Ministry of Health (2012) “Appendix B.29: Treatment of multiple sclerosis (ICD-10 G 35), available at <http://www.ptsr.org.pl/pl/?poz=Top/B/B10/80>

93 MS Ireland (2013) “Emma Talks at Polish MS Society event”, available at <http://www.ms-society.ie/blog-articles/1357-emma-invited-to-polish-ms-society>

94 Polish Ministry of Health (2015) Letter from the Minister of Health to President of the Polish Society of Multiple Sclerosis (Mr. Tomasz Poleć) – Warsaw, 18 June 2015, PLA.4600.216.3.2015

95 EMSP (2008) “Code of Good Practice in MS”. Available at: <http://www.emsp.org/wp-content/uploads/2015/07/European-Code-of-Good-Practice-english-version.pdf> [Accessed on 08 October 2015].

*Guidelines*

To assess the role of clinical guidelines we need to look at the extent to which they exist, how recently they have been updated, and the degree to which they are influential in the use of medicines.

All countries studied have developed clinical guidelines. These are either produced by official independent health agencies such as NICE in the UK or the Haute Autorité de Santé (HAS) in France, or by professional organisations such as the German Society of Neurology (DGN) or the Swedish MS Association.<sup>96</sup>

In Germany, France and Spain, these guidelines are not statutory, and although they are largely followed, clinicians remain free to prescribe as they see fit, in accordance with the treatment label. For example, in Germany, the German Society of Neurology (DGN) and the Competence Network on Multiple Sclerosis (Kompetenznetz Multiple Sklerose – KKNMS) issue medical guidelines for the treatment of MS, and respondents confirmed that these guidelines are comprehensive and highly consistent with each other.<sup>97,98</sup> Similarly, in France, HAS developed a number of clinical guidelines for the treatment of MS, addressed to doctors but also patients.<sup>99</sup>

Other countries have developed guidelines that provide clear and comprehensive recommendations on DMD initiation and monitoring, and these determine the extent of treatment coverage. In the UK, there are multiple documents that provide guidance around the clinical condition and the options the treatment for MS. In England more specifically, the following documents include some form of recommendations on treatment options and clinical management of MS:

1. A commissioning policy for DMDs from NHS England<sup>100</sup>,

96 The Swedish MS Association is a professional organisation for researchers and caregivers of MS patients. The association includes researchers, neurologists, rehabilitation-clinicians, nurses, occupational therapists, physiotherapists, almoners, speech therapists and psychologists.

97 Deutsche Gesellschaft für Neurologie (2014) "Multiple Sklerose: Empfehlungen aus der aktualisierten Leitlinie der DGN". Available at: <http://www.dgn.org/presse/pressemitteilungen/2782-multiple-sklerose-empfehlungen-aus-der-aktualisierten-leitlinie-der-dgn> [Accessed on 06 October 2015].

98 Rieckmann, P. and Toyka, K.V. (1999) "Klinische Forschungsgruppe für Multiple Sklerose und Neuroimmunologie, Neurologische Universitätsklinik, Würzburg, Deutschland". *European Neurology* Vol 42 Issue 3 pages 121-127. Available at: <http://europepmc.org/abstract/med/10529535> [Accessed on 06 October 2015].

99 Haute Autorité de Santé (2006) GUIDE – AFFECTION DE LONGUE DURÉE, "Sclérose en plaques", accessible at [http://www.has-sante.fr/portail/upload/docs/application/pdf/07-024\\_sclerose-guide\\_sans\\_lap.pdf](http://www.has-sante.fr/portail/upload/docs/application/pdf/07-024_sclerose-guide_sans_lap.pdf) [Accessed on 06 October 2015].

100 NHS England (2014) Clinical Commissioning Policy: Disease Modifying Therapies for Patients with Multiple Sclerosis (MS) accessible at: <https://www.england.nhs.uk/wp-content/uploads/2013/10/d04-p-b.pdf> [Accessed on 06 October 2015].

2. a prescribing guideline from the Association of British Neurologists<sup>101</sup>,
3. a set of criteria for auditing and reimbursing DMDs<sup>102</sup>,
4. a draft prescribing algorithm from NHS England.

Some respondent, notably patients and clinicians pointed out that “all these documents are developed separately and are often inconsistent”. This can create confusion in a landscape where there is already some important variation in prescribing practice.<sup>103</sup> Despite the ABN guidelines, some respondents noted a lack of clinical consensus amongst physicians over the benefit of prescribing certain DMDs, and some scepticism with regards to DMDs and early prescribing of treatment as a whole. This was attributed to “patchiness” in the neurologist’s level of knowledge of the available MS treatments, particularly the newer therapies.<sup>104</sup>

In Sweden, there are MS Society (SMSS) guidelines that provide clear and comprehensive recommendations on DMD initiation and monitoring.<sup>105</sup> These clinical guidelines cover DMD treatment but less so other aspects of MS care and management (symptomatic treatment; non-pharmacological care). As a result, respondents communicated that the Swedish Health Board is currently developing national clinical guidelines.

In Poland, the Ministry of Health and NFZ have developed very detailed and stringent clinical guidelines that include details as to the lesions in imaging diagnostics (meaning in magnetic resonance scans), the EDSS score, and the number of relapses.<sup>106</sup> General guidelines on MS care are issued by the Polish Neurological Society, and the last version was issued in 2012.

According to research, clinical guidelines need to be updated when there are changes in evidence, the values placed on evidence, the resources available for healthcare, and improvements in current performance. Whilst most countries have developed guidelines that were released or updated recently, HAS in France issued a number of clinical guidelines in 2006 which many respondents indicated are now out of date and do not include the latest therapies and should therefore be updated.<sup>107</sup>

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101 Scolding, N., Barnes, D., Cader, S., Chataway, J., Chaudhuri, A., Coles, A., ... & Shehu, A. (2015). Association of British Neurologists: revised (2015) guidelines for prescribing disease-modifying treatments in multiple sclerosis. *Practical neurology, practneurol-2015*.

102 NHS England (2015) Medicines note reimbursed through national prices and directly commissioned by NHS England. Version 9.1 published November 2015, accessible at: <https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2015/04/nhs-drugs-list-mar15.pdf>

103 Interview with a patient association in the UK

104 Interview with an MS neurologist in the UK

105 Svenska MS-sällskapet. “Metodboken”. Available at: <http://www.mssallskapet.se/Metodboken.html> [Accessed 06 October 2015].

106 Interview with Polish payer; mz.gov.pl

107 Haute autorité de sante (2006) GUIDE – AFFECTION DE LONGUE DURÉE, “Sclérose en plaques”, accessible at [http://www.has-sante.fr/portail/upload/docs/application/pdf/07-024\\_sclerose-guide\\_sans\\_lap.pdf](http://www.has-sante.fr/portail/upload/docs/application/pdf/07-024_sclerose-guide_sans_lap.pdf)

**Figure 6: National treatment guidelines in selected countries**

Countries	Guidelines	Developed by
<b>France</b>	HAS guidelines for doctors (2014)	Haute Autorité de Santé (HAS)
<b>Germany</b>	DGN Guidelines (2014)	German Society of Neurology (DGN) and the Kompetenznetz Multiple Sklerose (KKNMS)
<b>Poland</b>	General guidelines on MS (2012)	Ministry of Health and the National Health Fund (NFZ) Polish Neurological Society
<b>Spain</b>	Regional guidelines	e.g. Multiple Sclerosis Foundation and the Generalitat of Catalonia
<b>Sweden</b>	National guidelines for treating MS in Sweden (to be completed in 2016) <sup>108</sup>	Swedish Health Board
<b>United Kingdom</b>	ABN guidelines (2015) NICE guidelines (2014)	Association of British Neurologists (ABN) National Institute for Health and Care Excellence (NICE) NHS England

*Patient choice*

Respondents in all countries indicated that the choice of treatments are, to an extent, chosen jointly by the clinician and the patient. Ideally, a neurologist will guide the discussion and will involve the patient in the decision-making process to the extent possible.

However, this clearly varies by country. France and the UK reflect different ends of the spectrum. For example, in France, clinicians indicated that a patient may have a say in treatment options and may decide if she/he wants to initiate the treatment and when to end it. The patient chooses the treatment to follow, as long as her/his conditions fit the product indication. For example, a patient may choose a certain beta interferon rather than another if

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MSIF (2014) News & Events – Swedish government to develop national guidelines. See more at: <http://www.msif.org/news/2014/09/19/swedish-government-to-develop-national-guidelines/#sthash.pewK5g9K.dpuf>

she/he prefers its administration criteria.<sup>109</sup> The patient also has a say in the choice of therapeutic treatment (physiotherapy, psychotherapy, etc.).<sup>110</sup>

In the UK, it has been defined as part of the NICE guidelines that patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals.<sup>111</sup> However, there were concerns expressed by respondents that this guideline is not followed and that patients often do not have the opportunity to make a joint decision with the neurologist on treatment choice. In particular, the MS Society (one of the patient associations) found that 35% of all patients not on treatment have never had a conversation with the neurologist about treatment.<sup>112</sup>

In Poland and the Czech Republic, treatment restrictions allows less scope for patient involvement. Patients are consulted and are allowed to swap first-line drugs in the case of adverse effects or partial treatment failure. Patients are treated for 1 year and then must be re-evaluated. However, the active participation of patients is less clear.

### 3.3. Implications and good practices

Once diagnosis has been made, timely access to appropriate treatment varies widely across the selected countries. Whilst all countries have developed clinical guidelines that provide clear and comprehensive recommendations on DMD initiation and monitoring, not all countries follow guidelines to the same extent. In Germany, France and Spain, guidelines are not statutory and are not linked to reimbursement restrictions. This means that neurologists are permitted to prescribe all approved DMDs with no reimbursement restrictions. This is linked to greater treatment flexibility and the ability to engage the patient more closely in the decisions around treatment options. Whilst countries like Spain, France and Germany have few reimbursement restrictions, the prescribing neurologists must demonstrate appropriate use of medicines (as indicated by the marketing authorisation) and adherence to clinical guidelines and approved indications.

The UK and Sweden have developed strict access conditions based on an assessment of value for money of new and existing treatments. Cost effectiveness analysis plays an important part in decision-making about the price and use of new drugs. The high prices of many new drugs also means that inappropriate use for patients who gain little or no benefit from the treatment creates a high “opportunity cost” in terms of health losses for other patients, for whom the

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109 Bayer AG. “Différentes options thérapeutiques”. Available at: <http://www.ms-diagnose.ch/fr/traiter-la-sep/traitement-a-long-terme/differentes-options-therapeutiques/index.php> [Accessed on 06 October 2015].

110 CRCHUM. “Aider les patients à apprendre à vivre avec la sclérose en plaques”. Available at: <http://crchum.chumontreal.qc.ca/bulletin-recherche-crchum/aider-les-patients-apprendre-vivre-avec-la-sclérose-en-plaques>. [Accessed on 06 October 2015].

111 NICE. “Multiple sclerosis: management of multiple sclerosis in primary and secondary care NICE Guidance CG 186”. Available at: <http://www.nice.org.uk/guidance/cg186/chapter/Patientcentred-care>. [Accessed on 06 October 2015].

112 Multiple Sclerosis Society (2014) “Life changing drugs out of reach for people with MS”. Available at: <http://www.mssociety.org.uk/ms-news/2014/04/life-changing-drugs-out-reach-people-ms> [Accessed on 06 October 2015].

resources could be better used. The extent to which this results in restriction in access differs across countries. Whilst both countries use cost effectiveness analysis, Sweden approves more reimbursement for MS treatment than the UK.

Poland and the Czech Republic have introduced conditions and other limitations on access to treatment. These include indirect restrictions on the number of MS patients eligible to receive DMD treatment due to limited value of contract between the National Health Fund and hospitals; geographical conditions such the requirement to be treated only within a specialised MS treatment centre; and clinical restrictions such as the need for a patient to meet certain criteria in order to qualify for reimbursement of DMDs. These restrictions introduce significant barriers to access to care, as well as significant delays.

In addition to the significant differences between countries, the interviews highlighted some policy actions that can accelerate the diagnosis and referral process.

In terms of good practices:

- **Develop clinically appropriate and up-to-date guidelines with flexibility to address specific patient needs.** All countries we looked at have developed clinical guidelines that provide clear and comprehensive recommendations on DMD initiation and monitoring. These should encourage and ensure best practice but also leave the physician freedom to prescribe the product that is best for the patient.
- **Promote and monitor appropriate use of medicines.** There are tools to ensure that prescribing neurologists demonstrate appropriate use of medicines and adherence to clinical guidelines and approved indications. This can include filing a prior-authorisation in order to confirm the reimbursement.<sup>113</sup> This allows more flexible cost control and monitoring of drug use.
- **Develop a scheme to provide temporary access to new treatments whilst new treatment is being reviewed/authorised.** Whilst many countries have substantial delays due to formal reimbursement procedures, temporary access conditions ensure patients have access to treatment until reimbursement authorities can review the product and carry out health technology assessment of the new drug. This can significantly reduce access delays.
- **Select treatment options in collaboration with the patient.** A neurologist will guide the discussion and will involve the patient in the decision-making process to the extent possible. Ideally, a patient should have a say in treatment options and can decide if and when she/he wants to initiate the treatment and when to end it. The patient chooses the treatment to follow as long as her/his conditions fit the product indication.

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Interview with Spanish neurologist.

## 4. The ongoing management of MS patients

In this chapter, we consider the ongoing management of MS through patient follow-up, treatment maintenance, organisation of care, the role of different specialists<sup>114</sup> and the importance of a multidimensional team, and the existence and accessibility of complementary healthcare services.

For the EMSP, good coordination between healthcare professionals and between the patient and healthcare professionals is essential for effective and timely care. Patients should be included within an interdisciplinary team of healthcare professionals and this should be coordinated by a single health professional who also acts as a “reference person” for the patient.<sup>115</sup> The availability of and access to MS nurses is also crucial to effective care.<sup>116,117</sup> Patients find the MS nurse a key player in the provision of information, support and advice, and a recent European Survey (MS NEED) identified that 31% of nurses in Europe believe there is room for improvement in the standards of MS care. In fact, the EMSP has made one of its priorities the goal of obtaining adequate numbers of MS nurses by 2020.<sup>118</sup> Lastly, the empowerment of people with MS to actively participate in their care management plays an important role; the EMSP stresses the importance of “timely provision of accessible information and advice” for both MS patients and those close to them.<sup>119</sup>

### 4.1. Patient follow-up and maintenance of treatment

In all of the countries studied, clinical guidelines recommend clinical monitoring at relapses and switching therapies if there is more than one relapse while on therapy. MRI monitoring should be used to check the disease activity of individual patients. All countries indicated that MRIs should be done every 12 months or after situations where there is uncertainty about the inflammatory activity (early in the disease, after therapy change, etc.).

There do not appear to be systematic differences between countries:

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114 As set out in “Managing Progressive MS: MANAGING MAJOR CHANGES”, there are a range of different specialists who could have a role to play in the treatment of MS: neurologist, family physician, MS nurse, physical therapist, occupational therapist, speech/language pathologist, social worker, counsellor, neuropsychologist.

115 EMSP (2008) “Code of Good Practice in MS”. Available at: <http://www.emsp.org/wp-content/uploads/2015/07/European-Code-of-Good-Practice-english-version.pdf> [Accessed on 08 October 2015].

116 Ibid.

117 EMSP (2014) “Code of Good Practice in MS”. Available at: <http://www.emsp.org/media/revised-code-of-good-practice/> [Accessed on 08 October 2015].

118 Ibid.

119 Ibid

- In Poland, patients are seen every 1 to 3 months in some hospitals, although monitoring occurs more often in children and adolescents.<sup>120</sup> Some patients who have less extreme symptoms or who are on less intensive treatments are seen just once a year. In Poland most of the patients actively treated visit hospitals on a monthly basis, as drugs are dispensed to them in hospital wards or pharmacies. Recently some hospitals have begun dispensing medicine for a 3-month period, and the requirements of the drug programme (diagnostic tests, blood samples) *impose frequent visits to the hospital or outpatients' clinic – at least once every 3 months.*
- In Spain, blood tests are provided every 6 months and MRIs are given every year. However, in some of the more remote hospitals, monitoring is less frequent.
- In Germany, the frequency of monitoring depends on the treatment prescribed<sup>121</sup> and the severity/progression of MS. According to respondents, patients typically have a neurologist consultation and receive an MRI once a year (patients on some DMDs require more regular monitoring for blood tests). These neurologist consultations usually last 15 to 30 minutes, and if a neurologist is unavailable, then a general physician is consulted. Regular physician or nurse consultations occur every 3 to 6 months for a stable patient and more frequently (every 1 to 3 months) for an unstable patient.
- In Sweden, respondents told us, treatment monitoring after diagnosis is the responsibility of the nurse. Directly after treatment initiation, patients can expect to be seen every few days by a nurse and then every 6 to 12 months thereafter.<sup>122</sup>
- In France, patient monitoring is shared between the neurologist and to some extent the PCP. Patient follow-up is provided annually, typically by a neurologist typically in the ambulatory setting. There is no prescribed standard monitoring regime, but follow-up by MRI and by MS nurses is designed according to the patient's condition.<sup>123</sup>
- In the UK, once treatment has been initiated, NICE guidance recommends that all patients with MS should have a comprehensive review of all aspects of their care at least once a year by a healthcare professional with expertise in MS and its complications.<sup>124</sup> Patients are encouraged to see their MS nurse at least every 6 months (more frequent monitoring may be required according to the treatment regime

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120 Polskie Towarzystwo Stwardnienia Rozsianego (2015) "Leczenie Stwardnienia Rozsianego (ICD-10 G 35)". Available at: [http://www.ptsr.org.pl/dane/files/Leki/zalacznik\\_b29\\_2015-05.pdf](http://www.ptsr.org.pl/dane/files/Leki/zalacznik_b29_2015-05.pdf) [Accessed on 06 October 2015].

121 Interview with German KOL neurologist – August 2015

122 Interview with Swedish MS nurse

123 HAS (2007) Guide d'affection Longue Duree : La prise en charge de votre maladie, a sclérose en plaques Vivre avec une sclérose en plaques, accessible at : [http://www.maladie-chronique-travail.eu/sites/default/files/ressources-documentaires/2Prise\\_en\\_charge\\_SEP\\_HAS.pdf](http://www.maladie-chronique-travail.eu/sites/default/files/ressources-documentaires/2Prise_en_charge_SEP_HAS.pdf)

124 NICE. "Multiple sclerosis: management of multiple sclerosis in primary and secondary care NICE Guidance CG 186". Available at: <http://www.nice.org.uk/guidance/cg186/chapter/Patientcentred-care>. [Accessed on 06 October 2015].

or in the case of a relapse). Yet in reality, the extent that these guidelines are followed varies according to the availability of healthcare professionals.

**Table 12: Summary of patient monitoring**

	<i>CZ</i>	<i>FR</i>	<i>DE</i>	<i>PL</i>	<i>SE</i>	<i>ES</i>	<i>UK</i>
<b>Neurologist visit</b>	No routine time frame identified	Every 6 months  Note: Routine follow-up is undertaken by a PCP	Every 12 weeks	Every month  Every 3 months	Every 12 months	Every 3 months  Every 6 months	Every 12 months (not necessarily neurologist, but healthcare professional with MS expertise)
<b>MRI monitoring</b>	Every 12 months	No routine time frame identified	Every 12 months	Every 12 months	Every 12 months	Every 12 months	No routine time frame identified
<b>MS nurse visit</b>	No routine time frame identified	No routine time frame identified	Every 3 months  Every 6 months	No routine time frame identified. In real life the same frequency as visit to neurologist	Every 6 months  Every 12 months	No routine time frame identified	Every 6 months

Source: Interviews with German neurologist, German patient association; Polish neurologist; Swedish neurologist, Swedish payer; Spanish neurologist; UK MS nurse. Letter from Polish Multiple Sclerosis Society; France – Sept & Vous;

As illustrated in Table 12, there are routine consultations with neurologists across countries, on an annual basis in Sweden and the UK, and more frequently in France, Germany, Spain and Poland (every 1, 3 or 6 months). Only the Czech Republic does not have a set time frame for neurologist visits. In terms of MRI monitoring, 5 out of seven countries provide scans annually (Czech Republic, Germany, Poland, Sweden, and Spain) while France and the UK do not prescribe MRI examinations at a particular time interval. Also noteworthy is the practice of involving other healthcare professionals in the monitoring of MS. In France, PCPs may be seen more frequently than neurologists. The MS nurse is also routinely involved in some countries; in Germany, Sweden and the UK, there are routine MS nurse consultations (every 3, 6, or 12 months).

#### *Treatment switches*

In the Czech Republic, France, Germany, Spain, and Sweden, there appear few issues with respect to switching treatment. A patient might be switched to another medication if he/she does not respond to the first-line medication, if the disease evolves and progresses, and if more lesions show up on the patient's MRIs. In Spain, criteria for switching medications are well

outlined in the regional clinical guidelines (e.g. Catalonia).<sup>125</sup> However, it was noted that in cases where first-line treatment is not effective, there could be more frequent follow-up with the patient as this would facilitate quicker access to effective medicines. Likewise, there are clear criteria for treatment switching in the Czech Republic.<sup>126</sup> Yet we heard from the Czech Republic patient association that second-line treatment criteria could be adjusted in order to provide quicker access of more effective treatments to more patients.<sup>127</sup> The Swedish landscape is different as there is no clear hierarchy of medicines presented in current clinical guidelines and there is little guidance on when one patient should be given one drug instead of another. This aspect will be covered in the forthcoming national guideline (to be published in 2016).<sup>128</sup>

In the UK, the Clinical Commissioning Policy on the use of DMDs for MS patients provides guidance on when to start and stop drug use.<sup>129</sup> We heard from respondents that there are few issues within this part of MS care but that there may be areas in the UK where there is restricted access to some treatments. In particular, some local healthcare providers have treatment escalation policies that allow the use of certain medications only after other medications have been found insufficient.

In Poland, criteria for switching are clearly described in both first-line and second-line drug programmes. On the one hand, patients are allowed to swap first-line drugs in the case of adverse effects or partial treatment failure (if relapses increase in number and severity or if an MRI shows more than one new GD+ lesion or more than two new variations of T2 lesions).<sup>130</sup> However, there are some patients who do not meet the criteria for either first- or second-line treatment – for example, patients who have JC virus antibodies. In practice there is an issue with the lack of reimbursed options available for a subgroup of patients with rapidly evolving severe disease who are JCV+ (fingolimod is not reimbursed for rapidly evolving severe disease) and for subgroups of patients who failed on first-line products, are JCV+ and have contraindication to fingolimod.<sup>131</sup> In addition, there are annual re-evaluations of the efficacy of treatment, and this evaluation determines whether or not a patient may continue on treatment.

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125 CEMCAT (2012) “Clinical practice guideline on the management of people with multiple sclerosis”. Available at: [http://www.cem-cat.org/wp-content/uploads/2015/07/Clinical\\_practice\\_guideline\\_on\\_the\\_management\\_of\\_people\\_with\\_multiple\\_sclerosis.pdf](http://www.cem-cat.org/wp-content/uploads/2015/07/Clinical_practice_guideline_on_the_management_of_people_with_multiple_sclerosis.pdf) [Accessed on 07 October 2015].

126 Interview with Czech Republic neurologist.

127 Interview with Czech Republic patient association.

128 MS International Federation (2014) “Swedish government to develop national guidelines”. Available at: <http://www.msif.org/news/2014/09/19/swedish-government-to-develop-national-guidelines/> [Accessed 07 October 2015].

129 NHS England (2014) Clinical Commissioning Policy: Disease Modifying Therapies for patients with MS, NHS England Clinical Reference Group for Neurosciences NHS England /DO4P/b

130 Polskie Towarzystwo Stwardnienia Rozsianego (2015) “Leczenie Stwardnienia Rozsianego (ICD-10 G 35)”. Available at: [http://www.ptsr.org.pl/dane/files/Leki/zalacznik\\_b29\\_2015-05.pdf](http://www.ptsr.org.pl/dane/files/Leki/zalacznik_b29_2015-05.pdf) [Accessed on 06 October 2015].

131 Interview with Polish neurologist.

There is no time limitation on the duration of treatment provision for first-line treatments, but for second-line treatments, provision is limited to 5 years.<sup>132</sup> Furthermore, second-line treatment provision is restricted to 34 hospitals.<sup>133</sup>

#### 4.2. The role of healthcare professionals

MS treatment necessitates multidisciplinary care that involves various healthcare professionals (HCPs). Indeed, according to the interviews, in most countries various medical staff are involved in the management and coordination of patient care. Traditionally, two main HCPs – the PCP and the neurologist – have been integral in the diagnosis and management of MS patients. In all countries (except for Sweden, where patients may self-refer to a neurologist), the PCP is crucial in initiating the diagnostic confirmation of MS by referral to a neurologist. Next, the neurologist is typically responsible for the diagnosis (although ophthalmologists and other specialists may also confirm a diagnosis if symptoms allow). Thereafter, care provision is complex, with the neurologist and PCP having varying roles in the management of care. Recently, we have seen the rise of care coordination and provision by nurses (including specialised MS nurses).

##### *The role of the PCP and neurologist*

The relative role of primary care doctors and neurologists varies across countries, with neurologists having a more important role in some countries for ongoing follow-up care. In Germany, Sweden, the Czech Republic and Spain, neurologists are most involved in guiding treatment choices and managing patient care. Respondents in Germany indicated that the neurologist will spend 1 hour with the patient after diagnosis to explain and agree on treatment options. After treatment initiation, respondents recognised that, typically, the neurologist is expected to remain the main point of contact for the patient, prescribing medicines and coordinating the patient's care with other healthcare professionals. This is confirmed by published literature, which found 85.7% of Interferon  $\beta$ -1a and 1b was prescribed by neurologists in 2009.<sup>134</sup> Similarly, in the Czech Republic, neurologists play an integral part in the provision of treatment as patients may only receive treatment in specialised MS centres under the supervision of a neurologist. In the UK, neurologists do not necessarily see MS patients on a regular basis but provide specialist care and management when required.<sup>135</sup>

132 Letter from Tomasz Poleć, Chairman of the Polish Multiple Sclerosis Society. [mz.gov.pl](http://mz.gov.pl)

133 Ibid.

134 Hoer Schifffhorst, G., Zimmerman, A., Fischaleck, J., Gehrmann, L., Ahrens H., Gunther, C., Sigel, K-O., Osowski U., Klein, M., and Bleb, H-H. (2014) "Multiple sclerosis in Germany: data analysis of administrative prevalence and healthcare delivery in the statutory health system". Available at: <http://www.biomedcentral.com/1472-6963/14/381> [Accessed on 06 October 2015].

135 Queen Elizabeth Hospital Birmingham. "Meet the Multiple Sclerosis Team". Available at: <http://www.uhb.nhs.uk/ms-team.htm> [Accessed 06 October 2015].

PCPs work in conjunction with – or in some cases in the place of – neurologists, and their role varies across countries: in two countries, PCPs provide supplementary care to patients. Specifically in Spain, PCPs are crucial members of MS multidisciplinary care teams, and in the Czech Republic, PCPs are responsible for prescribing symptomatic medication.<sup>136,137</sup> The role of the PCP is much greater in France and Germany, where the PCP may assume responsibility for some of the patient follow-up care. In France, the neurologist regularly informs the PCP about the patient's condition (breakouts, minutes of consultations, etc.). The PCP is usually an important link who can make the connection between different specialists and keep each of them in the loop of the patient care pathway. This then simplifies and enables optimal management of the patient. The PCP is also in charge of the dossier ALD (long-term illness status).<sup>138</sup> He/she ensures the coordination of care between different healthcare providers and healthcare facilities.<sup>139</sup>

Care is much less led by neurologists and PCPs in the UK and Poland, where MS nurses play a crucial role.

#### *The role of nurses*

Many countries have introduced specialised MS nurses who play a major role in providing information and education to MS patients and their families. Their role involves coordinating and organising care for the patients and communicating in order to support them in managing their disease, as well as updating and monitoring patient registry data.

In some countries, we observe an increasing trend in the availability and involvement of nurses in MS care (e.g. UK, Poland). Some respondents in the UK indicated that MS nurses are often very effective and more cost efficient than neurologists. According to NICE guidance, in 2001, a professional membership organisation was created for MS patients – the UK MS Specialist Nurse Association (UKMSSNA).<sup>140</sup> In 2014, there were 245 full-time-equivalent MS specialist nurse posts in the UK; 75% of these nurses were employed by acute trusts and the remainder by community providers.<sup>141</sup> Similarly, in Spain, nurses act as the link between the patient and the multidisciplinary team; they encourage patient autonomy and ensure that care remains of

136 Interview with Czech Republic general practitioner.

137 AEDM (2015) "Tratamiento". Available at: <http://aedem.org/esclerosis-m%C3%BAltiple/tratamiento> [Accessed on 06 October 2015].

138 Carenits. Traitements de la sclérose en plaques. Prise en charge de la SEP. Interlocuteurs privilégiés pour la SEP.

139 SEP Ensemble (2014) Who's who des interlocuteurs médicaux, Le médecin généraliste (MG), accessible at <http://www.sep-ensemble.fr/Ma-Sep-au-quotidien/Mon-parcours-de-soin/Who-s-who-des-interlocuteurs-medicaux#832> [Accessed on 19 November 2015].

140 Multiple Sclerosis Trust. "UKMSSNA (UK MS Specialist Nurse Association)". Available: [http://www.mstrust.org.uk/atoz/ms\\_nurse.jsp](http://www.mstrust.org.uk/atoz/ms_nurse.jsp) [Accessed 06 October 2015].

141 Multiple Sclerosis Trust. "MS Specialist nurses". Available: [http://www.mstrust.org.uk/atoz/ms\\_nurse.jsp](http://www.mstrust.org.uk/atoz/ms_nurse.jsp) [Accessed 06 October 2015].

quality.<sup>142</sup> In 2013, there were 100 MS nurses in Spain.<sup>143</sup> We heard that as most MS nurses are funded by their own MS departments through grants, rather than by the hospitals, this leads to underfunding for these healthcare professionals.<sup>144</sup>

Even countries that primarily rely on neurologists and PCPs for care coordination increasingly involve nurses. In Germany, MS nurses have the role of informing and advising patients on the disease, treatment options, MS organisations, diet, sport and treatment administration. Respondents further found that MS nurses often provide more than just technical assistance: they build a relationship of trust with patients, reducing their fears and coaching treatment adherence. MS nurses are generally found in specialised MS centres and are generally funded by sick funds (social health insurance). However, these HCPs are often sponsored by pharmaceutical companies and, as a result, the availability of MS nurses across Germany varies. Respondents in Germany indicated that there are an insufficient number of MS nurses, especially independent MS nurses. The need for MS nurses is well recognised in Germany, and since 2007 the DMSG in Germany offers an online-based qualification programme for MS nurses called “MS Nurse Professional”. This service is also coordinated by the EMSP and is available in many countries.<sup>145</sup>

Swedish respondents also felt that MS nurses could assume a greater role in care. MS nurses in Sweden already provide advice, counselling, administration of treatment and other aspects of patient follow-up, and they play an important role in facilitating coordination of care across the range of MS specialists. But, as there is relatively easier access to MS nurses than neurologists (albeit access also suffers from “postcode lottery”), respondents in Sweden felt that MS nurses could be given more freedom to prescribe medicines.

In France, however, there is no official specialised “MS nurse”, although the role of the nurse is not entirely dissimilar to what we have just described. Nurses act as a link between the patient and the multidisciplinary team and look to encourage patient autonomy and ensure that care remains of quality.

However, the role of MS nurse is clearly changing over time. Indeed, in France, Sweden and Germany, we are seeing a trend to towards greater involvement of nurses in MS care.

#### 4.2.1. Coordination of care within and across care setting

Pharmacological and non-pharmacological care is provided by a variety of care disciplines which may or may not be located in a single setting or geographic location. Therefore the

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142 Observatoria Esclerosis Múltiple, “Los profesionales de las unidades de esclerosis múltiple: el neuropsicólogo y la enfermera”. Available at: [http://observatorioesclerosismultiple.com/esp/profesionales-rol\\_y\\_funciones/los\\_profesionales\\_de\\_las\\_unidades\\_de\\_esclerosis\\_multiple\\_el\\_neuropsicologo\\_y\\_la\\_enfermera/detalle.html#.VZQBVPiVhHw](http://observatorioesclerosismultiple.com/esp/profesionales-rol_y_funciones/los_profesionales_de_las_unidades_de_esclerosis_multiple_el_neuropsicologo_y_la_enfermera/detalle.html#.VZQBVPiVhHw) [Accessed on 06 October 2015].

143 2013 MS Atlas. Available at: <http://www.msif.org/about-us/advocacy/atlas/> [Accessed on 06 October 2015].

144 Interview with Spanish neurologist.

145 EMSP, MS Nurse Professional, accessible at: <http://www.ms Nursepro.org/>

coordination between care settings is crucial. In fact, the EMSP Code of Good Practice in MS calls for “collaborative work by the team, and other health professionals such as a dietician, together with the person affected by MS, to ensure planning, problem assessment, and goal setting in the long-term and short-term”.<sup>146</sup> We find that care coordination is a problem in all markets, both between healthcare professionals and between care settings. As a French respondent recounts, “Lack of coordination of care is one of the major problems in the treatment of multiple sclerosis as this results in a chaotic course of care for patients”.<sup>147</sup> According to the respondents, coordination is important both between specialist centres and between different care provision models.

Based on the interviews, there are significant differences in how care is organised:

- Some countries focusing on specialised MS care centres.
- Other countries provide ongoing care primarily in the hospital setting.

In three countries, the way the coordination works between specialised MS care centres was seen as an important factor in the provision of treatment.

Germany has specialised MS centres providing outpatient care, which are financed by the health insurance funds. The national MS patient association (DMSG) has set up its own criteria to assess these “MS care centres”. According to their assessment, there are approximately 150 clinics that have the ability to treat MS patients unequally dispersed in Germany. Of these, only 73 have the appropriate DMSG MS centre certification.<sup>148,149</sup> We heard from respondents that MS centres are further categorised into “specialised” and “non-specialised” centres, differentiated by the presence of MS nurses (specialised centres typically have MS nurses). Care within these centres is generally well coordinated, as these centres often have their own data tracking system.

In the Czech Republic the role of specialised centres was seen as important. Care is centralised in these clinical treatment centres, and there are 15 such centres located around the country. They offer not only comprehensive clinical care but also non-clinical care services (e.g. physical therapy) under one roof. Alternative and rehabilitative care is usually covered by a local foundation. Through a project called MS Rehab, patient associations are working to implement comprehensive care in more treatment centres around the country. They are perceived to be an effective way to a centralised skill set and ensure the coordination of care between the various dimensions of MS. However, not all centres have equally qualified personnel, and there are some differences in quality of care. The four MS treatment centres in Prague are perceived to offer better and more efficient treatments, and as a result are often overwhelmed with

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<sup>146</sup> EMSP (2008). “Code of Good Practice in MS”. Available at: <http://www.emsp.org/wp-content/uploads/2015/07/European-Code-of-Good-Practice-english-version.pdf> [Accessed on 08 October 2015].

<sup>147</sup> Interview with French clinicians “médecine physique et de réadaptation”

patients. Some centres also accrue significant waiting periods for patients to be treated, especially in Prague, where waiting time can exceed 6 months.

In the UK there are specialist MS centres where care coordination is reported as satisfactory. According to the MS Trust, there are approximately 70 MS treatment and 25 MS specialist centres across the UK.<sup>150</sup>

Although specialised care centres were seen as particularly important parts of the German and UK models, it was noted that care is also provided in general hospitals and clinics in both countries.

In other countries, the role of specialist centres was less important, with care being provided within the hospital setting, but coordination remained a significant issue.

Sweden does not have formal specialised MS centres that provide both pharmacological and non-pharmacological care. Although there are no dedicated MS centres at national level, there are MS specialty units available in each county. These often hold specific MS teams that may provide support and assistance to MS patients and are present within larger university hospitals. According to a Swedish respondent, seven centres include neurology clinics with expertise in MS care.<sup>151</sup>

There are no care centres for MS in Spain and Poland. We heard from a Spanish respondent that only 100 out of 900 hospitals have neurology capabilities (8 out of 35 hospitals in Andalusia are able to treat MS patients).<sup>152</sup>

France has a similar situation in terms of the lack of specialised MS centres. There are currently 450 French hospitals that are seen as appropriate to treat MS patients (but not necessarily specialised).<sup>153</sup> There are currently no specialised centres dedicated to MS; however, hospitals have been equipped with different levels of specialisation and expertise. There are 3 levels:

- Level 1: standard hospital characterised by a single organisational model
- Level 2: more specialised with neurological unit and specialised clinical skills for MS
- Level 3: highly specialised centre that deals with complex and costly MS cases.

The Ministry of Health is currently consolidating the existing expertise and developing 24 clinical reference centres, which will be tasked with looking after patients with more advanced/complex cases of MS.

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150 Multiple Sclerosis Trust. "MS News". Available at: <http://www.mstrust.org.uk/news/article.jsp?id=6715> [Accessed on 06 October 2015].

151 Interview with Swedish neurologist.

152 Interview with Spanish neurologist.

153 Le Point (2014) "Sclerose en plaques: le classement 2014". Available at: <http://hopitaux.lepoint.fr/classement-75/sclerose-en-plaques.php> [Accessed on 06 October 2015].

However, the problems of coordination do not seem linked to a particular care model. Across the majority of the countries (Czech Republic, Germany, Poland, Spain, Sweden, the UK), respondents indicated that communication and coordination with community and/or outpatient provision centres is poor. In the UK, respondents pointed out that there is a lack of “comprehensive collaboration” between different healthcare units for MS. In particular, it was also mentioned that there is no direct communication between a nurse and any allied healthcare professionals, and this leads to inefficient and wanting care provision.<sup>154,155</sup>

The exception is France. Indeed, the absence of specialised care centres has not meant poor care coordination in France. Over the last 10 years, the French health authorities at regional level have developed “networks” (Reseaux SEP) to organise and facilitate the complementarity and coordination of all respondents involved in the care for people with MS.<sup>156</sup> Seventeen networks have been developed in France, about half of which are funded either through ambulatory care funds (FAQSV) or by *Regional health agencies (ARS)*. Health networks are designed to promote access and support that is tailored to the individual's needs, in terms of health education, prevention, diagnosis and care.<sup>157</sup> These networks have developed multidisciplinary institutions like “MS clinics”, which account for the different dimensions of the disability (e.g. neurological motor deficits, cognitive impairment, fatigue, pain, psychological distress, social disability). These network bring together different centres, independent HCPs such as neurologists, physical doctors, paramedics, social workers, and psychologists; and are usually managed by a small team of neurologists and nurses (coordination team).<sup>158</sup> Individuals within the network collaborate and regularly gather to exchange ideas and tools. In 2008, all the founders and presidents of the networks signed a charter in order to reinforce their collaboration.<sup>159</sup> More than 15 of these networks are part of the *Groupement national des reseaux de sante suivant des patients atteints de SEP*.

### 4.3. The provision of information

#### 4.3.1. The provision of information to patients

As highlighted by EMSP, the Code of Good Practice calls for the “timely provision of accessible information, informed advice and emotional support from diagnosis onwards on the

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154 Interview with UK MS nurse.

155 Galazka and Jaworska Interview; interview with KOL LL.

156 LFSEP (2015) “Comprendre la SEP → Les Réseaux SEP”. Available at: <http://www.ligue-sclerose.fr/Comprendre-la-SEP/Les-Reseaux-SEP2> [Accessed on 06 October 2015].

157 Article L 6321-1 of the Code of Public Health inserted the Act of March 4, 2002.

158 Reseau Rhone-Alpes SEP. “Qu’est-ce qu’un réseau de santé?”. Available at: <http://www.rhone-alpes-sep.org/accueil/le-reseau/quest-ce-quun-reseau/>. [Accessed on 06 October 2015].

159 Ibid

disease".<sup>160</sup> We find that patients have different pathways to obtaining information about the disease. They include joining patient support groups, consulting clinical guidelines, and turning to clinical staff for support.

#### *Guidelines targeted at patients*

In France, HAS developed a series of documents for MS patients (November 2007)<sup>161</sup> which provide information on the care pathway, including details of treatment options and care admission criteria. They also list all the medical professionals who will be involved in the care (PCP, neurologist, medicine MPR doctor (*médecine physique et réadaptation*), ophthalmologist and other specialists such as urologist, gynaecologist etc.). The patient has to be involved in the management of his/her disease and participate in decisions such as: which acts will be performed, and which treatments are available – both DMDs and symptomatic treatments.

Similarly, in the UK, NICE has developed clinical guidelines and made them available to all. These documents contain an entire section providing advice on the care and support that should be offered to people who use health and care services.

#### *The role of patient associations*

In all countries, we find that patient associations have taken on the role of looking after patients and providing them with the help and support they need in terms of guidance and quality information about the care pathways; however, it is also up to the neurologist to walk the patient through the key steps when the diagnostics are carried out. The neurologist deals with all the treatment linked to neurology (e.g. diagnostics, follow-up). France, the UK, and Poland, have several associations or groups (e.g. Ligue Française contre la Sclérose En Plaques, Observatoire Français de la Sclérose en Plaques in France; and the MS Trust, the MS Society, and Shift.ms in the UK; the Polish MS Society (PTSR) with 26 branches in Poland).

#### *The role of HCPs*

Communication between clinical professionals to share information regarding the patient varies widely across the country. Within well-functioning MS networks, clinicians maintain a database where they can share information on each patient, through the international database EDMUS held in hospital. However, some clinicians indicated that outside the MS networks, some patients seek treatment from several centres in different cities, and this information is not recorded, which leads to a breakdown in communication between PCP and MS specialists.<sup>162,163</sup> In countries with MS specialised nurses (UK, Sweden, Germany), these play

160 EMSP (2008). "Code of Good Practice in MS". Available at: <http://www.emsp.org/wp-content/uploads/2015/07/European-Code-of-Good-Practice-english-version.pdf> [Accessed on 08 October 2015].

161 HAS (2007) Guide ALD n° 25 – Guide patient : Vivre avec une sclérose en plaques, Novembre 2007. Accessible at [http://www.has-sante.fr/portail/upload/docs/application/pdf/2008-06/08-093\\_gp\\_sep.pdf](http://www.has-sante.fr/portail/upload/docs/application/pdf/2008-06/08-093_gp_sep.pdf) [Accessed on 19 November 2015].

162 Interview with French PCP.

163 Interview with French neurologist.

a major role in providing information and education to MS patients and their families. They coach people to live as healthily as they can, and, where possible, teach patients to self-manage their disease.<sup>164</sup>

#### 4.3.2. Understanding the evolution in the management of the disease

According to the EMSP, patient registries are crucial to further research on MS. Therefore, the EMSP created the European Register for Multiple Sclerosis (EUReMS) between 2011 and 2014 in collaboration with a number of academic institutions and non-governmental organisations in order to address the “lack of data at EU and national level on the treatment and care of people with MS”. To this end, EMSP continues to build an additional network of more than 10 national MS registries, citing the need to gather “data from all across the EU”. In particular, EMSP promotes and encourages the collecting, collating, and sharing of relevant MS data with the aim that by 2024 there is a collaborative development to share such data across Europe.<sup>165</sup>

With the objective to improve the knowledge and management of the disease, MS registries have been a tool for raising awareness among both clinicians and the general public, improving the management of care as well as facilitating post-marketing surveillance. All of the countries in our survey have developed some form of patient registry.

Table 13 provides an overview of national registries that have been developed in Europe, and highlights that none of the countries studied have a registry that covers all MS patients.

**Table 13: Overview of National MS registries/databases in Europe**

Country	Name of Registry/ Managing Institution	Year of creation	No of Centres	Coverage (patients in DB)
Czech Republic	Czech national registry (ReMuS)	2013	13	~30% <sup>166</sup>
France	EDMUS database	1976	59	40% <sup>167</sup>
German	REGIMS (KKNMS)	2001	161	35% <sup>168</sup>

<sup>164</sup> Ibid.

<sup>165</sup> EMSP (2014) “Code of Good Practice in MS”. Available at: <http://www.emsp.org/media/revised-code-of-good-practice/> [Accessed on 08 October 2015].

<sup>166</sup> There are 17,000-19,000 people with MS in CZ (<http://www.ksb.cz/en/news-publications/959/ksb-supports-multiple-sclerosis-patient-register>) and the ReMus has 5639 patient records ([http://www.multiplesclerosis.cz/docs/150525\\_aj\\_zaverecna-zprava\\_sablona\\_souhrnna\\_rocni.pdf](http://www.multiplesclerosis.cz/docs/150525_aj_zaverecna-zprava_sablona_souhrnna_rocni.pdf)) =

<sup>167</sup> EDMUS (2015) Utilisateurs d'EDMUS en France, juillet 2012, accessible at : [http://www.edmus.org/fr/proj/net\\_fr.html](http://www.edmus.org/fr/proj/net_fr.html)

<sup>168</sup> DMSG (2014) deutschlandweiten Multiple Sklerose Register der DMSG, Bundesverband e.V accessible at: <http://www.dmsg.de/msregister/index.php?nav=msregister>

Poland	REJSM <sup>a</sup>	2004		
Spain	Vall d'Hebron University	2008	20	-
Sweden	Swedish MS Registry	1997	61	78% <sup>169</sup>
UK	University of Swansea (pilot project)	2009	5	-
	MS Register (web-based survey + clinical study)	2014	13	12% <sup>170</sup>
Europe	European Register for Multiple Sclerosis (EUREMS)	2012	-	-

Source: <sup>a</sup> Rejestr Chorych ze Stwardnieniem Rozsianym; CRA interviews; Pugliatti, M. et al. (2012) Flachenecker, P. (2008, 2015); ReMuS Czech Republic MS Register (2014)

France was one of the pioneers of patient databases for MS and launched the EDMUS project (European Database for Multiple Sclerosis) in 1976 in Lyon. Its objective is to create a database of MS patient data that uses a common language in patient files in order to make it easy to select, exchange, compare and share data and files. This has greatly facilitated the monitoring of patients and the exchange of information among physicians.<sup>171</sup>

Another pioneer was Sweden, which established a patient registry in 1997. Currently, it is mandatory to register all diagnoses in a general nationwide data register (Swedish National Patient Register). In addition, there is a nationwide MS specific register (Swedish MS registry or SMSreg) created in 1997 and maintained by the Swedish Association of Local Authorities and Regions and the National Board of Health and Welfare with the involvement of the Karolinska Institute. This database includes elements such as the date of diagnosis, the disease course, and diagnostic examinations used. In 2014, the registry had 14,344 patients representing 78% of all MS patients.<sup>172</sup> The registry is updated by neurologists, MS nurses or any other participating caregivers who provide information on specific patients or on their entire county.<sup>173</sup> Respondents found that the MS registry is useful in providing evidence on the access to treatment, and giving power to clinicians seeking increases in budget from policymakers and

169 Svenska Neuroregister, NEUROreg (2014) Årsrapport 2013-2014, accessible at : <http://www.neuroreg.se/Content/Files/%C3%85srappport%202013-2014.pdf>

170 UKmsregister.org website, accessible at <https://www.ukmsregister.org/Portal/Home#about>

171 The EDMUS project website. Available at: <http://www.edmus.org/en/proj/index.html> [Accessed on 06 October 2015].

172 Svenska Neuroregister, NEUROreg (2014) Årsrapport 2013-2014, accessible at : <http://www.neuroreg.se/Content/Files/%C3%85srappport%202013-2014.pdf>

173 Boström, I. (2012) "Epidemiological Studies of Multiple Sclerosis in Sweden with focus on the County of Värmland". Available at: <http://www.diva-portal.org/smash/get/diva2:480873/FULLTEXT01.pdf> [Accessed on 06 October 2015].

administrators. However, some respondents also cautioned that the information in these registries is not representative of reality, as there may be missing information.

Other countries in this study – namely Germany, the UK, Poland and Spain – still lack fully fledged patient registries. Although Germany established the REGIMS-Register (established and led by KKNMS) in 2001, it remains limited in the number of medical centres participating.<sup>174</sup> In the UK, the UK MS Society and Swansea University have developed a web-based survey launched in 2014; patients with a confirmed diagnosis of MS can self-register and respond to a simple multiple choice questionnaire on how MS affects their day-to-day life. In addition, a clinic-based study is taking place in 13 selected NHS hospitals and treatment centres across the UK. A team of experts is involved in collating and analysing data. The clinical study and online survey form the MS Register. So far, 12,650 people have joined the study.<sup>175</sup>

In general, respondents indicated that the current data available on MS patients is inadequate and a more complete patient registry is desired. Spain has a national registry, coordinated by the Spanish society of neurology, but only 9 of the 17 regions contribute to it and data remains limited. A voluntary registry in Catalonia tracks newly diagnosed patients and epidemiological data. This focuses only on the incidence and prevalence of MS and does not track information about patient access and outcomes. As it stands currently, KOLs do not believe it could be expanded to influence national policies.<sup>176</sup> In Poland, the National Health Fund collects patient medical records data on the monitoring and treatment of patients in drug programmes for MS, although they generally do not freely grant access to the data.<sup>177</sup> However, MS data for Poland is generally estimated and sporadically collected. A proposal for a National Treatment Programme for MS treatment<sup>178</sup> which included the collection of patient data was introduced in 2006 but was never fully implemented. Some stakeholders indicated that Poland has been leveraging the European register (EUReMS) developed by the EMSP. The REJSM is the Polish MS register but covers only a part of the country.<sup>179</sup>

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174 Interview with German KOL neurologist.

175 UKmsregister.org website, accessible at <https://www.ukmsregister.org/Portal/Home#about>

176 Interview with Spanish neurologist.

177 Polskie Towarzystwo Stwardnienia Rozsianego (2015) "Leczenie Stwardnienia Rozsianego (ICD-10 G 35)". Available at: [http://www.ptsr.org.pl/dane/files/Leki/zalacznik\\_b29\\_2015-05.pdf](http://www.ptsr.org.pl/dane/files/Leki/zalacznik_b29_2015-05.pdf) [Accessed on 06 October 2015]. [www.mz.gov.pl](http://www.mz.gov.pl)

178 Broła, W. et al. (2013) "Need for creating Polish registry of MS patients". Available at: <http://www.ncbi.nlm.nih.gov/pubmed/24166570> [Accessed on 06 October 2015].

179 Flachenecker, P., Buckow, K., Ellenberger, D. and Hillert, J. (2014) "Assessment of the patients' perspective in the European Register for Multiple Sclerosis (EUReMS): Study protocol and first results of the PRO study". Available at: [http://www.eurems.eu/attachments/article/105/ECTRIMS\\_2014\\_EUReMS\\_PRO\\_final\\_A0.pdf](http://www.eurems.eu/attachments/article/105/ECTRIMS_2014_EUReMS_PRO_final_A0.pdf) [Accessed on 06 October 2015].

Finally, the Czech Republic had a national initiative for a MS registry in 2004.<sup>180</sup> According to respondents, this register is largely used by payers and authorities to compare data from centres and to determine budget impacts of new treatments. However, the registry does not include any way to measure the relative effectiveness of drugs and does not include all patients.<sup>181</sup> There are other efforts to collect MS registry data, namely the Impuls Foundation, which currently holds data of 5,000 patients,<sup>182</sup> and also MSBase, an ongoing, longitudinal, strictly observational registry open to all practicing neurologists and their healthcare team and which includes contributions from the Czech Republic.<sup>183</sup>

#### 4.4. Complementary care services

The EMSP recognises the need for complementary care services to address and manage MS associated symptoms and disability. The EMSP Code of Good Practice states that patients should have “access to non-pharmacological therapies and rehabilitation services (which includes neurology, rehabilitation medicine, nursing, physiotherapy, clinical psychology, social counselling, occupational therapy and speech therapy) throughout a patient’s life as their omission “severely diminishes the quality of life” and can “lead to missed opportunities to more effectively manage the progression of the disease”.<sup>184,185</sup>

EMSP also recommends “adequate and appropriate community care services including home adaptations ... to enhance mobility and independence” of the patient.<sup>186</sup> Furthermore, the EMSP notes, at the very late stages of disease development, “palliative care assessments and services” should be a patient right. Such care should be “co-developed” by the MS patient and his/her specialist care team.

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180 Ministerstwo Zdrowia, “Narodowy program leczenia chorych ze stwardnieniem rozsianym na lata 2006-2008”. Available at: [http://www2.mz.gov.pl/wwwfiles/ma\\_struktura/docs/zalacznik\\_r\\_22.pdf](http://www2.mz.gov.pl/wwwfiles/ma_struktura/docs/zalacznik_r_22.pdf) [Accessed 07 October 2015].

181 Interview with Czech Republic payer.

182 Valkova, Hana (2014) “Šetříte na léčbě roztroušené sklerózy, vyčítá státu přední neuroložka”. Available at: [http://zpravy.idnes.cz/biologicka-lecba-roztrousena-skleroza-dy3-/domaci.aspx?c=A141016\\_125400\\_domaci\\_hv](http://zpravy.idnes.cz/biologicka-lecba-roztrousena-skleroza-dy3-/domaci.aspx?c=A141016_125400_domaci_hv) [Accessed on 06 October 2015].

183 MSBase Registry website, accessible at <https://www.msbase.org/>

184 EMSP (2008) “Code of Good Practice in MS”. Available at: <http://www.emsp.org/wp-content/uploads/2015/07/European-Code-of-Good-Practice-english-version.pdf> [Accessed on 08 October 2015].

185 EMSP (2014) “Code of Good Practice in MS”. Available at: <http://www.emsp.org/media/revised-code-of-good-practice/> [Accessed on 08 October 2015].

186 EMSP (2008). “Code of Good Practice in MS”. Available at: <http://www.emsp.org/wp-content/uploads/2015/07/European-Code-of-Good-Practice-english-version.pdf> [Accessed on 08 October 2015].

#### 4.4.1. Rehabilitation and physiotherapy

Across the countries interviewed, physiotherapy and rehabilitative care is difficult to access and is under-prescribed by neurologists and physicians. We find that the barriers to access vary from country to country:

- Restricted service provision due to uncoordinated source of funding: In Germany, respondents stated that few health insurances had provisions for complementary care despite the DMSG (patient association) recommending the use of complementary therapies such as massages and relaxation respiratory therapy to support symptomatic treatment.<sup>187</sup> Physiotherapy is covered by the social health insurance (SHI) funds. All services and prescriptions within the SHI must meet the German law and G-BA-guidelines, which in some cases restricts reimbursement of complementary care to very specific medical needs. A similar situation occurs in the UK, where guidelines are often not specific about the usefulness or the desirable qualities of complementary care, thereby leading to a lack of public coverage of these services.
- Restricted service provision due to insufficient funding: According to one MS group, the Spanish public health system has insufficient means to meet the demand for rehabilitative treatment. Currently, patients in Spain are entitled to receive rehabilitative services only once a year or less.<sup>188</sup>
- Restricted service provision in certain geographic areas: In Sweden and France there is fragmented access to complementary services. In both countries, there is generally greater service availability in urban cities as compared to rural areas, in line with the availability of healthcare professionals.<sup>189</sup> In Sweden, a survey by the Swedish MS Association concluded that a majority of Swedish neurology units and neurology clinics do not think there are sufficient resources for the rehabilitation of persons with MS.<sup>190</sup> Similarly, in France, rehabilitation for MS patients is well coordinated by a rehabilitation specialist called an MPR doctor (*médecine physique et réadaptation*), who takes charge of the patient's functional rehabilitation and also coordinates the action of other HCPs to assist in rehabilitation. However, access to such specialised rehabilitation services is generally provided outside the hospital setting (outpatient care) and according to a French specialist, there are important gaps in the management complementary care for MS patients. In particular, it is very difficult to find a physiotherapist or an MPR in less populated areas.

187 DMSG. "Treating MS". Available at: [http://www.dmsg.de/ms-behandeln/index\\_en.html](http://www.dmsg.de/ms-behandeln/index_en.html) [Accessed on 06 October 2015].

188 Interview with Spanish Physiotherapist.

189 Interview with Swedish KOL, Patient association, policy experts.

190 SMSS (2007) MS-sällskapets Rehabiliteringsdag Torsdagen 20/9 2007 Rehab survey – conducted by the rehabilitation committee, accessible at: <http://mssallskapet.se/rehabenk.pdf>

But countries like the Czech Republic, Poland and Spain that have poor availability and access to complementary care (see Figure 7) are addressing the issue by creating specialised MS rehabilitation centres.

- In the Czech Republic, 15 clinical treatment centres dedicated to MS offer comprehensive care for patients, including physical therapy; and alternative and rehabilitative care is usually covered by a local foundation. Through a project called MS Rehab, patient associations are working to implement comprehensive care in more treatment centres around the country.
- In Poland, the National Health Fund is offering MS patients only some general rehabilitation programmes, typically addressed to all types of neurology patients. To help increase access to specialist MS rehabilitative care, Poland's Department of Prevention and Rehabilitation at the Social Insurance Authority is planning to launch a rehabilitation scheme for patients with MS.<sup>191</sup> Currently, patients can get several consultations with different specialists in one day, so patients who may live far away from the centre only have to travel once. There are also two specialised rehabilitation centres in Poland for MS patients, which offer 3-week courses co-financed by social care and the patients themselves once every two years. These aim to specialise services for patients with higher levels of disability.
- In Spain, the Spanish Association of MS, AEDEM-COCEMFE, is attempting to fill this gap in availability by creating comprehensive rehabilitation centres where patients can have access to a multidisciplinary teams comprised of rehabilitation physicians, physiotherapists, psychologists, social workers, occupational therapists, speech therapists, and nurses.

What was described by respondents is very much in line with the data from the MS Barometer. As Figure 7 illustrates, rehabilitative care across countries is limited. According to the 2013 MS Barometer, Germany stands out as a country with good access. However, we heard from respondents that, in practice, limitations to care remain because of health insurance reimbursement policies.

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Interview with Polish neurologist.

**Figure 7: Access to rehabilitation care**

<b>Country</b>	<b>Number of MS patients for 1 rehabilitation clinic</b>	<b>Max distance to a rehabilitation clinic/ care</b>	<b>Access to outpatient rehabilitation</b>	<b>Access to inpatient rehabilitation</b>
<b>Czech Rep</b>	0 MS rehabilitation clinics	Between 50 and 100 km	As often as required	Limited by health insurance rules
<b>France</b>	-	-	-	-
<b>Germany</b>	1 clinic for <1500 MS patients	Less than 50 km	As often as required;	As often as required
<b>Poland</b>	1 Clinic for >2500 MS patients	Over 200 km	Less than once per year	Less than once per year
<b>Spain</b>	0 MS rehabilitation clinics	Less than 50 km	Less than once per year	Less than once per year
<b>Sweden</b>	1 Clinic for <1000 MS patients	Over 200 km	Limited by health insurance rules	Less than once per year
<b>UK</b>	1 Clinic for >2500 MS patients	Over 200 km	Limited by health insurance rules	Limited by health insurance rules

Source: 2013 MS Barometer

#### 4.4.2. Palliative care

“Palliative care” is an area of healthcare that focuses on relieving and preventing the suffering of patients from their symptoms.<sup>192</sup> The EMSP Code of Good Practice says that “people affected severely by MS” should have “the right to palliative care assessments and services”.<sup>193</sup>

Respondents indicated that palliative care is not well organised for MS patients in most countries (the Czech Republic, Germany, Poland, Spain, Sweden and the UK), and is often reserved for other types of disorders and diseases. For example, respondents said that palliative care in Poland is reserved mostly for cancer patients,<sup>194</sup> and that in Germany there is little integration of palliative care with traditional MS care.

#### 4.4.3. Support for the patient through disability benefits

An element of ongoing care provision is also financial, including support through disability benefits. The EMSP Code of Good Practice says that at advanced stages, patients should receive “adequate and appropriate community care services including home adaptations, assistive technologies and technical aids and supported housing to enhance mobility and independence”. In our survey we also explored to what extent support for disabled MS patients varies across the seven countries. Across countries, we observe that there are no national disability programmes for MS but that MS patients can access the assistance available to all disabled people. The general disability assistance covers two categories: assistance with daily living, and provisions to maintain and support employment.

In France, MS patients are entitled to some level of disability compensation benefits, customised autonomy allowances, disability allowances, fiscal support, and easier access to credit. Indeed, the social care support for disabled patients is generous in France, but is highly fragmented, and access to medical and social assistance systems is extremely difficult for dependent patients.<sup>195</sup> Health insurance that covers complementary care is difficult to obtain for patients with long-term disabilities and can be very expensive depending on the stage of the disease.

In Poland, there is a State Fund for Rehabilitation of Disabled People (Państwowy Fundusz Rehabilitacji Osób Niepełnosprawnych or PFRON) – a public authority set up in 1991 to support rehabilitation and employment of persons with disabilities.<sup>196</sup> The money from PFRON is

<sup>192</sup> EMSP (2013) MS Barometer 2013 Widespread health inequalities revealed. Available at: <http://www.ms-sep.be/userfiles/files/emsp/MS%20Barometer%202013.pdf> [Accessed on 06 October 2015].

<sup>193</sup> EMSP (2008). “Code of Good Practice in MS”. Available at: <http://www.emsp.org/wp-content/uploads/2015/07/European-Code-of-Good-Practice-english-version.pdf> [Accessed on 08 October 2015].

<sup>194</sup> Letter from Tomasz Poleć, Chairman of the Polish Multiple Sclerosis Society.

<sup>195</sup> Interview with French neurologist

<sup>196</sup> Państwowy Fundusz Rehabilitacji Osób Niepełnosprawnych. Website. Available at: <https://www.pfron.org.pl/>. [Accessed on 06 October 2015].

earmarked for the rehabilitation of disabled persons (assistance for the purchase of rehabilitation equipment, local rehabilitation centres, support groups, legal assistance, home rehabilitation, and the purchase of rehabilitation equipment and orthopaedic goods).<sup>197</sup> PFRON creates its own assistance programmes, and currently it is implementing several. However, some Polish respondents have noted that disability programmes specifically for MS patients are of low quality, largely because the Ministry of Health and the Ministry of Social Services are cutting costs from both sides.<sup>198</sup> There is also the Polish Association of Multiple Sclerosis with 26 branches throughout Poland that work with local organisations to provide assistance to disabled persons and organisations for people with MS from Europe and other continents. In addition, PFRON funding helps social insurance institutions lower the costs of employment of disabled persons, contributes to social insurance solidarity for disabled farmers and their family members (ASIF) and adapts jobs for people with disabilities.

Similarly, Sweden has multiple provisions and support for assistance with daily living and employment. The Swedish government provides financial assistance for transportation and disability in the form of subsidies. Sweden provides free accommodation modifications or group housing with 24-hour assistance for those in need, in accordance with their EDSS score. However, respondents in Sweden found that there were often delays in access to those services due to long waiting lists.<sup>199</sup> MS patients are also allowed to take long periods of sick leave, ranging from 2 to 12 weeks according to relapse severity, while maintaining employment.<sup>200</sup>

In the UK there seems to be greater emphasis on support for daily living. MS patients can receive help with covering extra costs to live independently (personal independence payment, disability living allowance, attendance allowance) and the inability to work (employment and support allowance).<sup>201</sup> However, interviewed respondents suggested that access to such financial assistance through disability benefits can take a considerable amount of time. Anecdotal waiting times for this support has been as long as 18 to 24 months in some cases particularly during recent periods of backlog and delay.

There are two countries that place more emphasis on maintaining and supporting the employment of disabled people.

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197 Polskie Towarzystwo Stwardnienia Rozsianego. "Kim jesteśmy?" Available at: [http://www.ptsr.org.pl/pl/kim\\_jestesmy\\_,174.asp](http://www.ptsr.org.pl/pl/kim_jestesmy_,174.asp) [Accessed on 06 October 2015].

198 Interview with Polish patient associations.

199 The official site of Sweden. "Sweden's disability policy". Available at: <https://sweden.se/society/swedens-disability-policy/> [Accessed on 06 October 2015].

200 Socialstyrelsen. "Sjukskrivning vid multiple skleros". Available at: <http://www.socialstyrelsen.se/riktlinjer/forsakringsmedicinsktbeslutsstod/multipelskleros> [Accessed 06 October 2015].

201 UK Government. "Financial help if you're disabled". Available at: <https://www.gov.uk/financial-help-disabled-and-sickness-benefits> [Accessed 06 October 2015].

In Spain, the concept of how to treat disability has changed – from focusing on assisting the recovery of functional abilities, to highlighting and eliminating obstacles to equal opportunities. All Spanish citizens are insured against disability and this guarantees his pension allowance. If the disability is a result of a common illness, the monthly base earnings are the insured's earnings in the last 96 months divided by 112. If the patient requires the constant attendance of others to perform daily functions, at least 45% of the pension is paid. For a total loss of working capacity in the usual job, the pension is 55% of the insured's monthly base earnings, but this may be increased to 75% of the insured's monthly base earnings if the insured is older than 55. For partial loss of working capacity – of at least 33% – in the usual job, the insured is paid a lump sum of 24 months of daily average earnings in the last calendar month before the disability began.<sup>202</sup>

Similarly, in the Czech Republic, pensions are maintained for people with disability. MS Disability pensions are paid for a total disability (70% loss of earning capacity) or partial disability (50% to 69% loss of earning capacity). The individual must have a minimum period of coverage according to the insured's age when the disability began. The full monthly disability pension consists of a flat-rate monthly amount of 2,170 koruna and an earnings-related amount of 1.5% of the personal assessment base per year of coverage. The projected coverage period is credited from the date the disability began up to the normal retirement age. The personal assessment base is calculated using average gross earnings in the last 10 years. For a partial disability, the monthly benefit is the flat-rate amount plus 0.75% of the personal assessment base for each year of coverage.<sup>203</sup> However, local experts believe that disability management is not good in the Czech Republic, as families do not get enough financial support and it is difficult for patients to continue working.

#### 4.5. Implications and good practices

We find that the wider management of MS varies greatly across the seven countries. Whilst patient follow-up and treatment maintenance is similar across all of the countries studied, with regular clinical monitoring at relapses and clear guidelines to switch therapies, there are important differences in the organisation of care, and the role and coordination of different MS specialists,<sup>204</sup> which lead to important differences in access to follow-up treatment and maintenance on treatment.

In Sweden, the Czech Republic and Spain, we find that neurologists are much more involved in guiding treatment choices and managing patient care. In France and Germany, the PCP is

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202 U.S. Social Security Administration: Office of Retirement and Disability Policy (2012) "Social security programs throughout the world: Europe 2012 – Spain". Available at: <http://www.ssa.gov/policy/docs/progdesc/ssptw/2012-2013/europe/spain.html> [Accessed on 06 October 2015].

203 U.S. Social Security Administration, Office of Retirement and Disability Policy. "Czech Republic". Available at: <http://www.ssa.gov/policy/docs/progdesc/ssptw/2010-2011/europe/czechrepublic.html> [Accessed on 06 October 2015].

204 As set out in "Managing Progressive MS: MANAGING MAJOR CHANGES", there are a range of different specialists who could have a role to play in the treatment of MS: neurologist, family physician, MS nurse, physical therapist, occupational therapist, speech/language pathologist, social worker, counsellor, neuropsychologist.

more involved in patient follow-up care and can assume responsibility for some of the oversight. Similarly, the role that specialised MS nurses play also varies widely, from providing information and education to MS patients and their families to coordinating and organising care for the patient. In all countries, nurses have played a key role in ensuring appropriate communication with patients to support them in managing their disease, as well as coordinating the effective management of patient care.

Another key aspect is the approach to coordinating the multidimensional aspect of MS care. Whilst some countries like Germany and the Czech Republic have developed acute care centres specialised in the treatment of MS consolidating the range of skills necessary to ensure the continuum of care, France has developed MS “networks” (Reseaux SEP) to ensure the coordination of care for people with MS. This has provided an effective mechanism to ensure greater levels of communication and coordination in the outpatient settings, thereby facilitating patient access at the local level.

There have been clear efforts across countries over the years to establish MS registries. Though none of the registries provide comprehensive coverage of all MS patients, their initiation by various stakeholders – academic institutions, professional and patient organisations – illustrate that there is widespread recognition of the need for data collection.

In the majority of countries, access to complementary healthcare services such as rehabilitative care, physiotherapy, and palliative care varies widely across patients and across regions. This does not seem to depend on wealth. In the UK and Sweden, access to these types of resources is limited and depends heavily on geographic location and access to MS treatment centres. As social care services are funded by local authorities in the UK, there are strong variations in access to complementary care services. An MS patient organisation based in the UK indicated that although some efforts have been made, there remains a strong “postcode lottery” for social care across the country.<sup>205</sup> Generally, there are more services available in urban cities than in rural areas where there are fewer HCPs.<sup>206</sup> While there are many contributing factors for the variation in complementary care services, the lack of integration between health and social care is certainly problematic. For instance, healthcare in Sweden is the responsibility of the county, whilst social care is the responsibility of the municipality. In situations such as these, patients may be shifted back and forth between different organisations, resulting in poor coordination of services and huge delays in access to rehabilitation and palliative care.

In addition to the significant differences between countries, the interviews highlighted some policy actions that can accelerate the diagnosis and referral process.

- **Designate a clear point of contact to ensure patient-centred care.** In Germany, Sweden, the Czech Republic and Spain, neurologists are much more involved in guiding treatment choices and managing patient care. But in other countries (e.g. France), a specialised HCP is designated to be in charge of rehabilitation and

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205 MS Society. “Physiotherapy,” Available at: <https://www.mssociety.org.uk/what-is-ms/treatments-and-therapies/physiotherapy> [Accessed on 06 October 2015].

206 Interview with UK policymaker.

coordination of care, in order to ensure greater coordination across care settings and over time, particularly for patients with long-term chronic and medically complex conditions such as MS who may find it difficult to 'navigate' fragmented healthcare systems.

- **Leverage specialised MS nurses appropriately.** In many countries, specialised MS nurses play a major role in providing information and education to MS patients and their families as well as coordinating and organising care for the patient. They also play a key role in ensuring appropriate communication with patients to support them in managing their disease, as well as keeping updates and monitoring patient registry data. MS nurses have an important coordinating role to ensure the effective management of patient care. However, nurses are often seen as a cost-effective resource and should not replace neurologists or other specialised care. The role should be clearly set out.
- **Strengthen specialised MS care centres.** Countries like Germany and the Czech Republic have developed acute care centres specialised in the treatment of MS. These hold specific MS teams that can provide support and assistance to MS patients and provide an effective way to consolidate existing skills in a fully coordinated manner, as well as to manage costs and monitor budget impact. A concern of the respondents was that while MS care is generally well coordinated in specialised MS centres (due to their own data tracking systems), MS care outside of these centres lacks coordination, as HCPs do not communicate with one another about the care.
- **Encourage multidimensional teams with fluid communication by formalising professional networks.** France has developed MS “networks” (Reseaux SEP) which have been created by the health authorities at regional level relatively recently (2004-2005) to organise and facilitate the complementarity and coordination of all respondents involved in the care for people with MS.
- **Collecting patient data through registries/databases.** Most countries have developed publicly available MS registries/databases in order to provide sufficiently detailed information on the provision of treatments, services and supplies within a given area that may be used to compare different levels of healthcare within and between these regions.<sup>207</sup> In the long term, MS registries will also serve to monitor the healthcare situation of MS patients over time.
- **Designate a person in charge** of the patient’s functional rehabilitation care. In France, rehabilitation services are handled by a rehabilitation specialist called an MPR doctor (*médecine physique et réadaptation*) who is in charge of the patient’s functional rehabilitation but also coordinates the action of other HCPs to assist in rehabilitation. However, access to such specialised rehabilitation services is general handled outside the hospital setting (outpatient care) and, according to local specialists, there are important gaps in the management of complementary care for MS patients.

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Flachenecker, P. (2008) “National MS registries”. *Journal of Neurology*, 255(6), 102-108.

- **Integrate health and social care services and funding:** In the UK, integration of health and social care is one of Scotland's major programmes of reform. Such integration ensures that patients get the right care and support at any point in their care journey, and it improves access to both health and social care by developing a single pooled budget for health and social care services to work more closely together in local areas, based on a plan agreed between the NHS and local authorities.<sup>208</sup>

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NHS England & Local Government Association (2013) Statement on the health and social care Integration Transformation Fund, NHS England Publications Gateway Ref. No.00314; accessible at <http://www.england.nhs.uk/wp-content/uploads/2013/08/itf-aug13.pdf>

## 5. Resources allocated to the treatment of MS

Finally, in this chapter we look at the amount of resources allocated to the treatment of MS and the level of financial coverage for long-term chronic disease such as MS.

Providing MS care requires significant resources. Adequate funding of MS services is therefore an important part of any sustainable system. EMSP's Code of Good Practice in MS does not provide any guidance on the level of resources that should be allocated to MS care by a healthcare system, but existing research suggests that low government spending in some countries leads to barriers in access.<sup>209</sup>

### 5.1. Resources allocated to MS

Given the relatively weak economic recovery in most European markets, it is not surprising that whilst health budgets have been increasing in most countries, the budget increases have not systematically kept pace with the rising costs of medicines and the total cost of MS. We heard from respondents in all countries that the sick funds and social health insurance funds are increasingly seeking to control costs and to influence and incentivise physicians to prescribe with that in mind. In terms of spending specifically on MS, few countries had a specific budget for MS or were able to identify how spending on MS was changing over time. We have attempted to gather estimates of the total cost associated to MS (including all healthcare costs) and the average cost per patient, and the extent to which these costs feed into resource allocation decisions. However, ensuring that the estimates are comparable across markets is challenging.

The budget allocated to MS was seen as particularly problematic in Czech Republic and Poland. In the Czech Republic, according to the interviews, there has been no budget increase for hospitals for pharmaceuticals since 2010, resulting in a high number of untreated patients. Treatment waiting lists were also put in place in 2011. We cannot find historical estimates of the average spending per MS patient, but the overall budget allocated to MS has increased, which will help more patients get treatment.<sup>210</sup> The General Health Insurance Company in the Czech Republic said that it would issue 1.2 billion koruna (€44.2 million) for the treatment of MS in 2015.<sup>211</sup>

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209 EMSP (2013) MS Barometer 2013 "Widespread health inequalities revealed". Available at: <http://www.ms-sep.be/userfiles/files/emsp/MS%20Barometer%202013.pdf> [Accessed on 06 October 2015].

210 Interview with Czech Republic payer.

211 Valkova, H. (2014) "Šetříte na léčbě roztroušené sklerózy, vyčítá státu přední neuroložka". [http://zpravy.idnes.cz/biologicka-lecba-roztrousena-skleroza-dy3-/domaci.aspx?c=A141016\\_125400\\_domaci\\_hv](http://zpravy.idnes.cz/biologicka-lecba-roztrousena-skleroza-dy3-/domaci.aspx?c=A141016_125400_domaci_hv) [Accessed on 6 October 2015].

In Poland, the average cost for patients on interferon treatment was approximately €6,412 to €12,000.<sup>212</sup> Each regional (voivodeship) branch of the NFZ has budget to treat patients within its region. This has created important differences in access to healthcare services across regions. It means some patients may end up travelling to other regions (e.g. Łódź or to Bydgoszcz) to seek treatment. However, funding for patient migration from one region to another comes from the local branch of NFZ, which further restricts local budgets. According to one KOL, MS is not a disease that the NFZ is focusing on relative to fields like cardiology, oncology, diabetes, etc., and allocated resources have been insufficient to address the needs of the existing MS patient pool.<sup>213</sup> However, a number of respondents noted that Poland has successfully implemented a scheme to allow taxpayers to contribute to supporting people with disability or with brain diseases. Taxpayers can choose to give 1% of their taxes to a non-profit organisation by indicating the desired recipient on their tax declaration form. This is one of the most significant and reliable income streams to the voluntary sector in Poland, as almost half of all taxpayers fill out this form. Some of the organisations that receive money from this programme include rehabilitative groups that can help provide support for MS patients, although they generally offer financial aid to several types of patients.<sup>214</sup> In Germany, France, UK, Sweden and Spain, there is not a specific budget allocated to MS, but respondents in these countries indicated that resources allocated to MS were seen as broadly adequate and were not a barrier to access. However, increasing pressure is being applied by payers to keep expenditure under control, and this is becoming a more significant issue.

- In Germany, the total annual spent on MS per patient is €23,087 which comprises direct medical costs (€17,165) and direct non-medical costs (€5,922 euros).<sup>215,216</sup> This estimation was confirmed by interviewed respondents, who found MS is one of the most expensive indications for health insurance companies, costing between €20,000 and €40,000 per patient (increasing with severity of disease).<sup>217</sup> Whilst the resources allocated to MS have been rising in Germany, so have the costs of MS treatment. With the rising costs of medicines and the total cost of MS increasing, we heard from

212 Szmurlo, D., Fundament, T., Ziobro, M., Kruntorádová, K., Dolezal, T., & Glogowski, C. (2014) "Costs of multiple sclerosis – extrapolation of Czech data to Polish patients". *Expert review of pharmacoeconomics & outcomes research*, 14(3), 451-458.

213 Interview with Polish payer.

214 Avalon Foundation. "How to donate 1% or donation to the beneficiary". [http://fundacjaavalon.pl/nasi\\_beneficjenci/jak\\_wplacic\\_1\\_lub\\_darowizne\\_na\\_rzecz\\_beneficjenta.html?662afe781ea10ccca6a1c443cb715f0c=43943a2f138835c53cd0020e04c99e0a](http://fundacjaavalon.pl/nasi_beneficjenci/jak_wplacic_1_lub_darowizne_na_rzecz_beneficjenta.html?662afe781ea10ccca6a1c443cb715f0c=43943a2f138835c53cd0020e04c99e0a) [Accessed on 6 October 2015].

215 <http://www.biomedcentral.com/1472-6963/14/381>

216 <http://de.statista.com/statistik/daten/studie/262541/umfrage/verteilung-der-durchschnittlichen-jahreskosten-einer-multiple-sklerose-erkrankung/>

217 Hapfelmeier, A., Dippel, F.W., Schinzel, S., Holz, B., Seiffert, A., and Maurer M. (2014) "Aktuelle Aspekte zur Versorgungssituation und zu den Behandlungskosten bei Patienten mit Multipler Sklerose in Deutschland". Available at: <https://www.thieme-connect.com/products/ejournals/abstract/10.1055/s-0033-1335883> [Accessed on 06 October 2015]

respondents that the sick funds are increasingly seeking to influence and incentivise physicians to prescribe with consideration in favour of more cost-effective options.

- In France, of the €147 billion spent by the social health insurance funds, €1,083 million (0.7%) were allocated to the coverage of multiple sclerosis patients.<sup>218</sup> The direct cost per patient and per year has been estimated at €10,640 with variations between regions.<sup>219</sup> The financing of drugs administered during a hospital stay is generally ensured through the “diagnosis related group” (DRG) system (tarification à l’activité or T2A) where the funding is provided by rates of hospitalisation benefits (GHS – homogeneous group stays), to cover the costs incurred as a lump sum. However, most MS drugs are covered by a special mechanism intended to ensure the financing of innovative and particularly expensive products. Most DMDs are therefore covered by additional funding, and products are listed on an “extra list” known as the “liste en sus”, which covers all billable drugs in addition to hospitalisation benefits.<sup>220</sup> Whilst prescriptions by specialists are generally free, the financing system for high-cost drugs means that health facilities must comply with “good prescribing” rules on the use of these expensive products due to their financial impact on the health insurance funds. In order to keep tabs on the prescribing of these products, health insurance funds have introduced “Good use contracts” known as “CBUS” (Contrats de bon usage des médicaments, des produits et des prestations).<sup>221</sup> These contracts aim to promote efficient use of medicines ensuring the appropriateness of drug prescriptions.
- In Sweden, according to published literature, the spending on an MS patient is highly correlated with the patient’s EDSS score. Specifically, the cost can range from €16,000 (EDSS score 0-1), to €116,000 (EDSS score 8-9).<sup>222</sup> We heard from respondents that pharmacological treatment costs remain a small proportion of total care costs and that social care or support is much more costly. Given budgetary pressures on local county healthcare budgets in Sweden, regional guidance usually recommends doctors prescribe the least costly drug. However, doctors maintain authority over prescriptions and often cite SMSS guidance to justify their prescription of more costly drugs. Respondents estimated the expenditure by the public healthcare system on DMDs per year ranged from approximately €8,300 to €20,000 annually per patient. Furthermore,

218 L’Assurance Maladie (2015) “Fiche pathologie: Personnes prises en charge pour autres affections neurologiques en 2013”, updated on 22/07/2015 CNAMTS/DSES/DEPP & DEOS, accessible at : [http://www.ameli.fr/fileadmin/user\\_upload/documents/Autres\\_affections\\_neurologiques\\_2013.pdf](http://www.ameli.fr/fileadmin/user_upload/documents/Autres_affections_neurologiques_2013.pdf)

219 Ibid.

220 Securite Sociale (2013) “Les médicaments de la ‘liste en sus’ Fiche éclairage extradite du rapport de la Commission des Comptes de la Securite Social” (Juin 2013), accessible at: [http://www.securite-sociale.fr/IMG/pdf/fiche\\_eclairage\\_4\\_medicaments\\_listes\\_en\\_sus.pdf](http://www.securite-sociale.fr/IMG/pdf/fiche_eclairage_4_medicaments_listes_en_sus.pdf)

221 <http://www.ars.paca.sante.fr/Contrat-de-bon-usage-CBU.127076.0.html>

222 Berg, J., Lindgren, P., Fredrikson, S., and Kobelt, G., (2006) “Cost and quality of life of multiple sclerosis in Sweden” *Eur J Heath Econ Suppl 2* : S75-85. Available at : <http://www.ncbi.nlm.nih.gov/pubmed/17310342> [Accessed on 06 October 2015].

for non-pharmaceutical healthcare expenditure, wealthier councils subsidise less wealthy county councils. There is no MS specific budget, so in the event of overspending on MS care, county councils would need to bear the consequences and modify spending on other healthcare services.

**Table 14: Annual total and per patient costs of MS**

	Germany	France	Spain	UK	Czech R	Sweden	Poland
<b>Total annual cost of MS</b>	-	€1083 million	€340 million	no estimates found	€200 million	€600 million	€300 million
<b>Total annual cost of MS per patient</b>	€23,087	€4,690	\$17,180	no estimates found	€6,258	-	€5,629

Source: Czech Republic – Pospíšková (2013); France – Ameli.fr; Germany – Das Statisk-Portal. (2015); Hoer et al. (2014); Spain – Kobelt (2009); Poland – Matschay et al. (2008); UK- Interviews with neurologists and patient associations; Poland – Szmurlo et al. (2014)

## 5.2. Financial coverage of MS care

In most countries, financial coverage for long-term chronic disease is generally high, with little out-of-pocket payment for clinical care. This is not the case for non-clinical care, where co-payment can be significant depending on the type of care.

Some countries have little or no co-payment for clinical MS care (PCP and neurologist consultation, pharmacological treatment, etc.).

- In Germany, the full cost of disease-modifying drugs is reimbursed from the sick funds without limits on duration of treatment, and the treatment of symptoms is also fully covered for MS-diagnosed patients.<sup>223</sup> For non-pharmacological treatment such as physiotherapy, the extent of reimbursement depends on the insurance company. In other words, rehabilitative care and physiotherapy are reimbursed, but the total number of funded sessions is usually restricted (If physicians prescribe more than certain levels, they can face fines) although if there is a medical reason for the prescriptions, additional sessions are not limited.
- Similarly, in the UK, all pharmacological treatments available to inpatients are free of charge. Outpatient medications are liable to the standard prescription co-payments, which are £8.20 in England (no co-payments in Scotland, Wales, Northern Ireland)

223

EurActiv (2014) "Data shows treatment inequalities for EU's multiple sclerosis patients". Available at: <http://www.euractiv.com/specialreport-brain-multiple-scl/data-show-great-health-inequalit-news-533623> [Accessed on 06 October 2015].

unless the MS patient is severely disabled and is thus exempted from prescription charges.<sup>224</sup> As for non-pharmacological care such as physiotherapy, respondents stated that patients are prescribed a certain number of free sessions from the PCP or neurologist and then must pay out-of-pocket for any additional care.<sup>225</sup>

- In Poland and the Czech Republic, co-payment is limited but access is restricted by site of care. In the Czech Republic, a patient must be admitted to an MS treatment centre in order to have access to treatment coverage. Each treatment centre has a special agreement with insurance companies that includes financial and prescription limitations. Inpatient medicines are reimbursed by the health insurance companies to the hospitals and other healthcare providers within a contracted lump-sum of money.<sup>226</sup> Patients can be treated after only one relapse or one instance of Clinically Isolated Syndrome (CIS). However, criteria for second-line treatments require patients to have two relapses within a year. Patients who do not meet treatment criteria can apply for a special condition to try and get reimbursement for their medicines from insurance companies. According to interviews, national insurance funds try to find a way to ensure these patients are treated. Once admitted to these centres in the Czech Republic, there is no co-payment required on any of the drugs issued there.<sup>227</sup> All patients who are financially able pay a co-pay for symptomatic treatments like physiotherapy. Co-pays are capped after a certain amount.

Other countries have some levels of co-pay but this remains relatively low and is not seen as a significant barrier to access:

- In Sweden, prescription drugs and health professional consultations require some level of co-payments. The annual co-payment for retail drugs has a maximum annual ceiling of SEK 2200 (€235) per patient and is independent of the patient's financial status. For prescription drugs that cost above SEK 5400 (€583), the patient is required to pay the entire co-payment upon initial collection from the pharmacy but is subsequently exempt from co-pay; all of the patient's prescription medicines are free of charge for the following 12 months. Similarly, drugs administered in hospitals (e.g. Tysabri, Lemtrada, rituximab) are free of charge to the patient. However, the patient has to pay for the hospital visit (although this is capped at €120 annually). Respondents indicated that

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224 The Walton Centre NHS Foundation Trust. "Your Information Prescription- Multiple Sclerosis". Available at: <http://www.thewaltoncentre.nhs.uk/uploadedfiles/documents/MS%20Prescripiton%20Information.pdf> [Accessed on 06 October 2015].

225 Multiple Sclerosis Society. "Physiotherapy". Available at: <http://www.Mssociety.org.uk/what-is-ms/treatments-and-therapies/physiotherapy> [Accessed on 06 October 2015].

226 Law Office Mareckova. "Pharmaceuticals in the Czech Republic". Available at: <http://www.pharmaceuticals-czech.com/prices-and-reimbursement> [Accessed on 06 October 2015].

227 Interview with Czech Republic payer.

the co-payments were not considered to be burdensome to patients. There are no financial assistance programmes to help MS patients with the co-payment fees.

- In Spain, in 2013, a controversial pharmaceutical hospital co-payment was implemented for all patients. Under the current regulation, each drug is subject to a maximum co-payment of 10% per container or a maximum of €4.2 per drug.<sup>228,229,230</sup> However, there were no specific issues associated to MS.
- In France, MS is one of the 30 chronic conditions specifically listed by the French healthcare system as a long-term disease (“affections de longue durée” or ALD) for which the main health insurance fund (CNAM<sup>231</sup>) provides full coverage of healthcare tariffs on the basis of the Social Security rate. The ALD applies to long-term conditions that require ongoing care (and potential withdrawal from the labour market) for over 6 months. This means that the various tests (MRI, ultrasound, blood test), and PCP consultations and medicines are reimbursed on the basis of the Social Security rate. However, co-payments and additional out-of-pocket payments may still occur, as patients will often face excess fees charged by specialists, which will often be covered by complementary health insurance. Indeed, for consultations with highly specialised consultants, additional fees apply, and fee rates over and above the Social Security rate are not uncommon. As a result, Social Security coverage of specialist treatment only reaches 70%. To cover the overruns and also the honorary hospital charge of €18 per day, patients are advised to sign up for a complementary health scheme. The ALD status is granted by the medical officer after presentation of a “care protocol” completed by the attending physician or specialist, specifying the diagnosis and treatment and all medical interventions entering into the patient’s care. One of the criteria of the ALD scheme is to be on disease modifying treatment as soon as a formal diagnosis has been established (even if there is no formal disability) or if disabled, a symptomatic treatment and care in the long term. Once the diagnosis of MS is made by a neurologist according to the diagnostic criteria in force, a request is sent to health insurance and validated by a CNAMTS physician.

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228 El Pais (2013) “Sanidad fija el copago de 42 fármacos de dispensación hospitalaria”. Available at: [http://sociedad.elpais.com/sociedad/2013/09/19/actualidad/1379614230\\_527574.html](http://sociedad.elpais.com/sociedad/2013/09/19/actualidad/1379614230_527574.html) [Accessed on 06 October 2015].

229 El Pais (2015) “Alonso da marcha atrás al copago hospitalario que impulsó Mato”. Available at: [http://politica.elpais.com/politica/2015/01/15/actualidad/1421337852\\_423063.html](http://politica.elpais.com/politica/2015/01/15/actualidad/1421337852_423063.html) [Accessed on 06 October 2015].

230 Esclerosis Multiple Espana (2014) “Rechazo al copago de fármacos de dispensacion hospitalaria”. Available at: [http://www.esclerosismultiple.com/noticias/detalle.php?id\\_not=466](http://www.esclerosismultiple.com/noticias/detalle.php?id_not=466) [Accessed on 06 October 2015].

231 The CNAMTS or Caisse nationale d’assurance maladie des travailleurs salariés, insures 87% of the French population (52,359,912 of the 60,028,292 inhabitants).

**Table 15: Financial Coverage and use of co-payment for clinical and non-clinical MS care**

	<i>CZ</i>	<i>FR</i>	<i>DE</i>	<i>PL</i>	<i>SE</i>	<i>SP</i>	<i>UK</i>
<b>Coverage of DMD and other clinical care</b>	100%	100% for DMD 70% for healthcare services	100%	100%	100%	100%	100% (for inpatient medication)
<b>Co-payment</b>	-	Some co-payment for PCP/neurologist visit – usually reimbursed by complementary health coverage	-	-	Annual co-payment for retail drugs – maximum annual ceiling of SEK 2200 (€235) per patient	10% per container or a maximum of €4.2 per drug	Co-payments of £8.20 (€11) for prescription in England
<b>Non-clinical care</b>	Co-pay for symptomatic treatments	-	-	-	-	-	-
<b>Restriction</b>	Restriction on number of rehabilitative care sessions funded	-	-	Restriction on number of patients and duration of treatment	Restriction on number of complementary care sessions (yoga, pilates) funded	-	Restriction on number of physiotherapy sessions funded

Source: CRA Analysis based on interviews

Financial coverage does not appear to affect access to care DMD and other clinical care services. However, greater levels of co-pay or other out-of-pocket payments are expected for some symptomatic treatments and non-clinical care services such as rehabilitation and other complementary care sessions.

### 5.3. Implications and good practices

Whilst health budgets have been increasing in most countries, according to respondents, the level of resources allocated to MS has not kept pace with the rising cost of new therapies.<sup>232</sup> Lack of resources was stated to be a particular problem in the Czech Republic and Poland, where respondents indicated this as being the main barrier to access to MS care. The issue of resources appears to be an even greater challenge at regional level, such as in Poland, Spain, and Sweden where important differences in resources and funding between regions were reported, leading to important differences in access within a country.

In addition to the significant differences between countries, the interviews highlighted some policy actions that can accelerate the diagnosis and referral process.

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Interviews with health professionals in Poland and the Czech Republic.

- **Develop complementary sources of funding for rehabilitation and disability support.** Innovative approaches should be used to encourage funding of complementary care. For example, taxpayers in Poland can currently choose to give 1% of their taxes to a non-profit organisation by indicating the desired recipient on their tax declaration form. This is one of the most significant and reliable income streams to the voluntary sector in Poland, which allows patient support organisations to fund rehabilitation programmes.
- **Develop a national strategy for MS to prioritise and streamline disease management.** Political leadership is essential to ensure consistency in the standard of care over time, to address the variations in service provision for people with MS, and to provide a framework to increase access more rapidly. This would serve to ensure that national registries are further developed and that clinical guidelines are kept up to date and more importantly that they are actually used in practice. The development of goals to achieve such strategies will ensure an assessment is made regarding the appropriate level of coverage to aim for.
- **Introduce a special coverage protocol for chronic conditions that require ongoing long-term care.** In France, the reimbursement authorities have a special reimbursement scheme which provides full coverage of healthcare costs for long-term conditions requiring ongoing care (and potential withdrawal from the labour market) for over 6 months. This provides exemptions from some "co-payments". As MS is one of the 30 chronic conditions specifically listed as "ALD exonérante", this means that the patient may benefit from 100% coverage by the social health insurance fund. The various tests (MRI, ultrasound, blood test), and PCP consultations and medicines are reimbursed on the basis of the Social Security rate. However, co-payments and additional out-of-pocket payments may still occur, as patients will often face excess fees charged by specialists, which will often be covered by complementary health insurance. Indeed, for consultations with highly specialised consultants, additional fees over and above the Social Security rate are not uncommon, and Social Security reimbursement only reaches 70%. To cover the overruns but also the honorary hospital charge of €18 per day, patients are advised to sign up for a complementary health scheme.

## 6. Policy implications: Identifying the challenges to access along the care pathway

Based on the assessment of good practice, the differences in management of care between countries, and the policies that different countries have implemented, this section applies these lessons to the care pathway in each of the case study countries. It explores where the challenges lie and to what extent these existing good practices can be leveraged on a country by country basis.

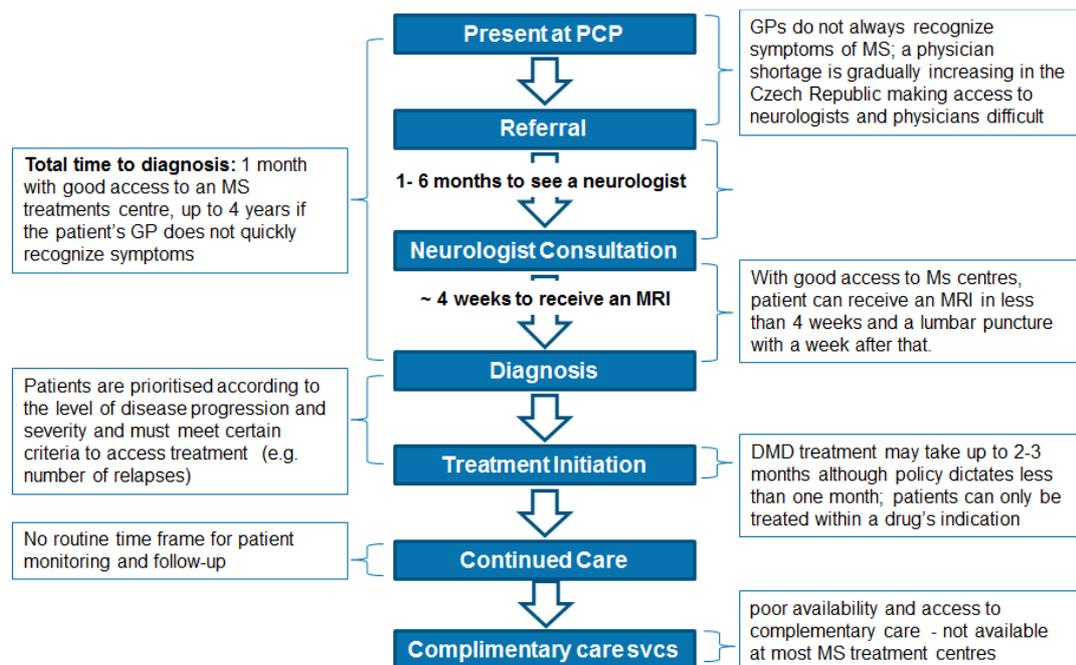
### 6.1. Country case studies

#### 6.1.1. Czech Republic

Barriers to access in the Czech Republic occur across the entire care pathway. This can be largely attributed to financial constraints associated with budget restrictions in hospitals and other MS specialised care centres, which translates into delays in access to MS centres, restrictions on access to treatment, and stringent ongoing treatment restrictions with little flexibility in treatment choice.

Once the patient is diagnosed and put on treatment, access to multidisciplinary care and patient follow-up is relatively more efficient, and complementary care services are accessible, although this can vary widely across regions. Comprehensive care is, however, not always available at most MS treatment centres. Figure 8 below summarises the different challenges to access along the MS care pathway in the Czech Republic, identified through the interviews.

**Figure 8: Challenges to access along the MS care pathway – Czech Republic**



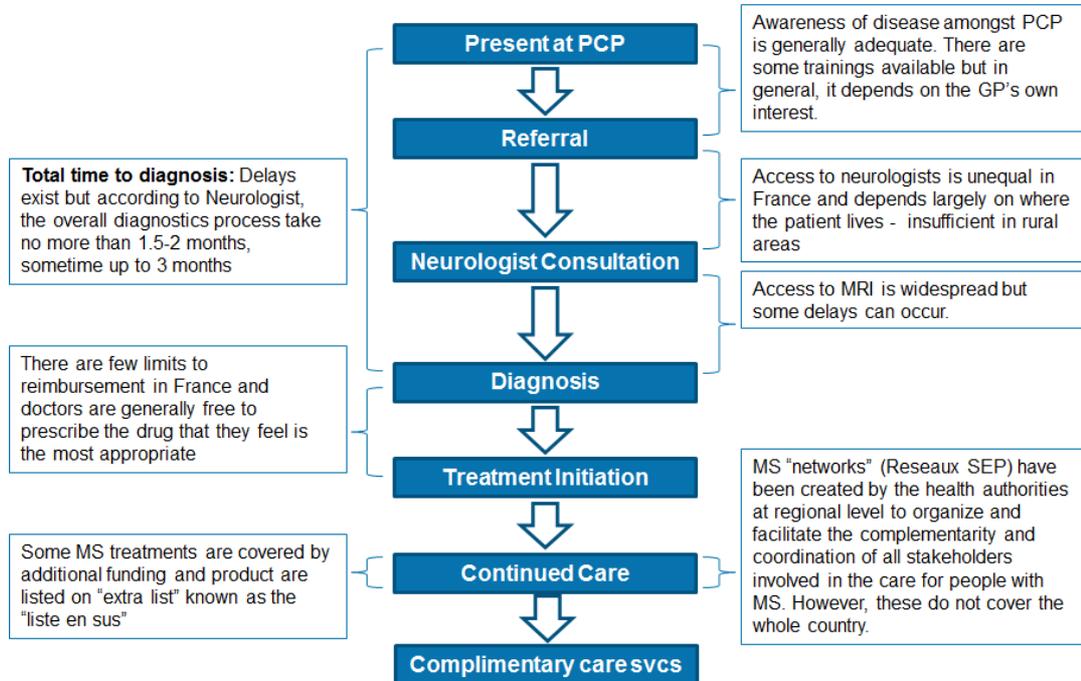
Source: CRA Analysis

Drawing on the comparison in the last chapter, there are a number of areas where policy initiatives could improve patient access:

- Improve patient awareness and physician awareness of the need to diagnose and treat MS early to overcome barriers to fast neurologist consultation for non-emergency patients.
- Support development of infrastructure to enable rural patients to access neurologists more quickly.
- Raise awareness of the need for comprehensive care in more treatment centres.
- Expand treatment criteria so that more patients are able to get access to effective treatment.
- Develop outpatient care facilities through networks to decongest MS treatment centres.
- Improve disability management so more patients can continue working.
- Investigate ways to support the development of the patient registry and include measures of relative effectiveness of MS treatments.

#### **6.1.2. France**

MS care in France is relatively well structured and there are few barriers at the early stage of the care pathway. Patients get referred to neurologists and diagnosed relatively quickly compared to other countries in Europe. Initiation of treatment is also relatively swift, and French patients benefit from timely access to appropriate drugs with a wide flexibility around treatment options. France appears to be experiencing challenges in ensuring the continuity of care post-diagnosis. Patient follow-up and access to complementary care (e.g. palliative care) is not well structured and lacks a clear focal point or reference person for the person affected by MS. Figure 9 below summarises the different challenges to access along the MS care pathway in France, identified through the interviews.

**Figure 9: Challenges to access along the MS care pathway – France**

Source: CRA analysis

Drawing on the comparison in the last chapter, there are a number of areas where policy initiatives could improve patient access:

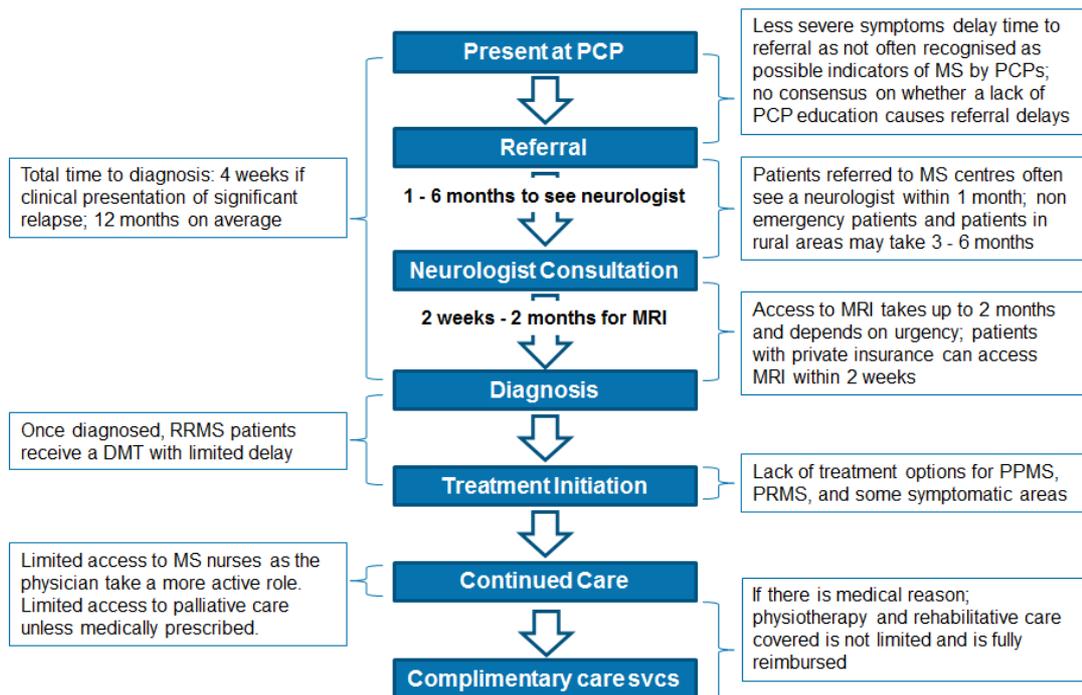
- Support development of infrastructure to enable rural/public insurance patients to access neurologists more quickly.
- Ensure greater coherence between clinical guidelines/recommendations and the organisation of care.
- Develop a comprehensive structure to follow the patient through the entire pathway by developing a patient-centric approach to ensure the continuity of MS care.
- Continue to promote the development of MS network and ensure a more homogeneous coordination of all stakeholders involved in the care pathway across regions.
- Increase focus on rehabilitative care and ensure greater availability of neurological rehabilitation in rural areas.
- Ensure greater integration between health and social care services and facilitate access to medical and social assistance systems.

### 6.1.3. Germany

There are few barriers to access to MS care in Germany. Patients are diagnosed relatively quickly thanks to a large network of neurologists and adequately trained PCPs. Reimbursement for MS treatment is high with few restrictions, follow-up care is well structured, and there are

few barriers at the early stage of the care pathway. However, like many other European countries, access to rehabilitative care and other complementary care services is under-prioritised, and access to these will vary widely depending on regional accessibility and differences in reimbursement conditions contingent on a patient's health coverage. Figure 10 below summarises the different challenges to access along the MS care pathway in Germany, identified through the interviews.

**Figure 10: Challenges to access along the MS care pathway – Germany**



Source: CRA Analysis

Drawing on the comparison in the last chapter, there are a number of areas where policy initiatives could improve patient access:

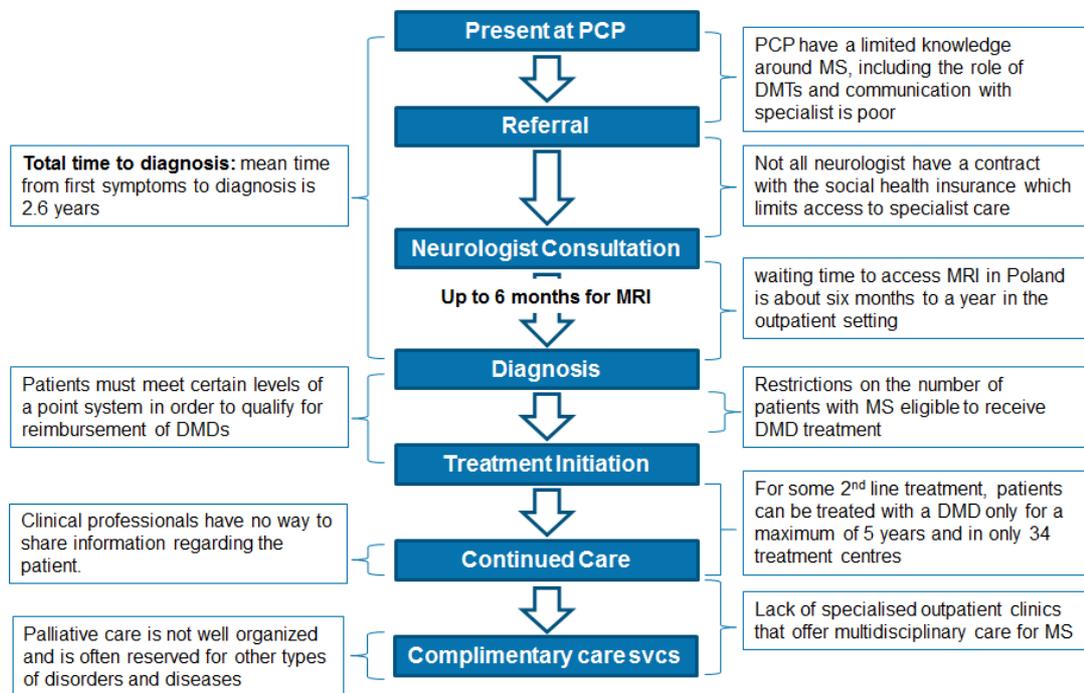
- Raise public awareness of MS symptoms to tackle delays in PCP presentation.
- Continue to raise awareness of the need to diagnose and treat MS early to overcome barriers to fast neurologist consultation for non-emergency patients.
- Support development of infrastructure to enable rural/public insurance patients to access neurologists more quickly.
- Investigate ways to support the development of the patient registry.

#### 6.1.4. Poland

There are many barriers to access to treatment in Poland starting with slow and inefficient referral and diagnosis. The level of awareness regarding multiple sclerosis is low even though the disease is gaining coverage; lack of resources means that the diagnosis remains slow and there are significant delays in putting patients on adequate treatment. Budgetary restrictions

have also led to the introduction of restrictions on the number of patients, the type of treatment options available, and the length of time that patients can remain on treatment. These are some of the key factors restricting access to multiple sclerosis treatments in Poland. Once patients are registered for the drug programme and enrolled in treatment, clinicians in Poland indicated that clinical management of the disease and patient follow-up is relatively better managed. However, it was acknowledged that lack of effective DMD treatment remains a problem, and that there is a need to improve rehabilitation and palliative care for MS patients in Poland, and that greater resources need to be allocated to support the continuum of care including social care in general. Figure 11 below summarises the different challenges to access along the MS care pathway in Poland, identified through the interviews.

**Figure 11: Challenges to access along the MS care pathway – Poland**



Source: CRA analysis

Drawing on the comparison in the last chapter, there are a number of areas where policy initiatives could improve patient access:

- Raise physician awareness of the need to diagnose and treat MS early to overcome barriers to fast neurologist consultation for non-emergency patients.
- Support development of infrastructure to enable rural/public insurance patients to access neurologists more quickly.
- Increase funding for MS and eliminate restrictions on the number of patients with MS eligible to receive DMD treatment.
- Reduce geographic barriers to second-line treatment by increasing the number of sites eligible to prescribe second-line DMD therapies.

- Remove 5-year restriction on DMD therapies for second-line therapies.
- Grant reimbursement to newer, more effective and comfortable treatments, e.g. orals, less frequently applied injections.
- Develop clinically appropriate and up-to-date guidelines with flexibility to address specific patient needs. Remove indication limitation on DMDs and focus on promoting and monitoring appropriate use of medicines.
- Increase funding for non-clinical care such as physiotherapy/rehabilitation, and encourage multidimensional teams with fluid communication by formalising professional networks.
- Investigate ways to support the development of the patient registry and include measures of relative effectiveness of MS treatments.

#### 6.1.5. Spain

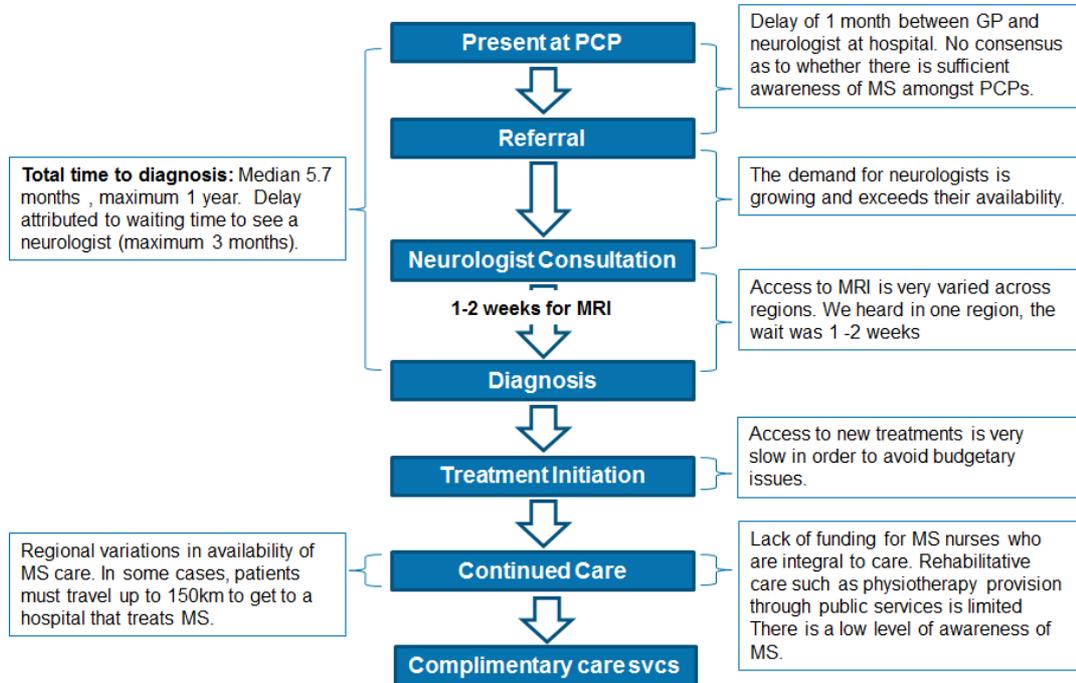
Access to MS care in Spain is relatively well structured and there are few barriers at the early stage of the care pathway. Diagnosis and initiation of treatment is conducted reasonably quickly and this was not necessarily seen a significant barrier. Once diagnosed, there are relatively few restrictions and limitations although access to treatment and care services can vary widely across regions. The Spanish health system is devolved, and each of its 17 regions has its own responsibility to regulate healthcare policy, planning and provision.<sup>233</sup>

We illustrate the challenges to access along the MS care pathway in Spain, identified through the interviews, in Figure 12 below.

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European Observatory on Health Systems and Policies (2010) "Health Systems in Transition: Spain Health System Review". Available at: [http://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0004/128830/e94549.pdf](http://www.euro.who.int/__data/assets/pdf_file/0004/128830/e94549.pdf)

**Figure 12: Challenges to access along the MS care pathway – Spain**

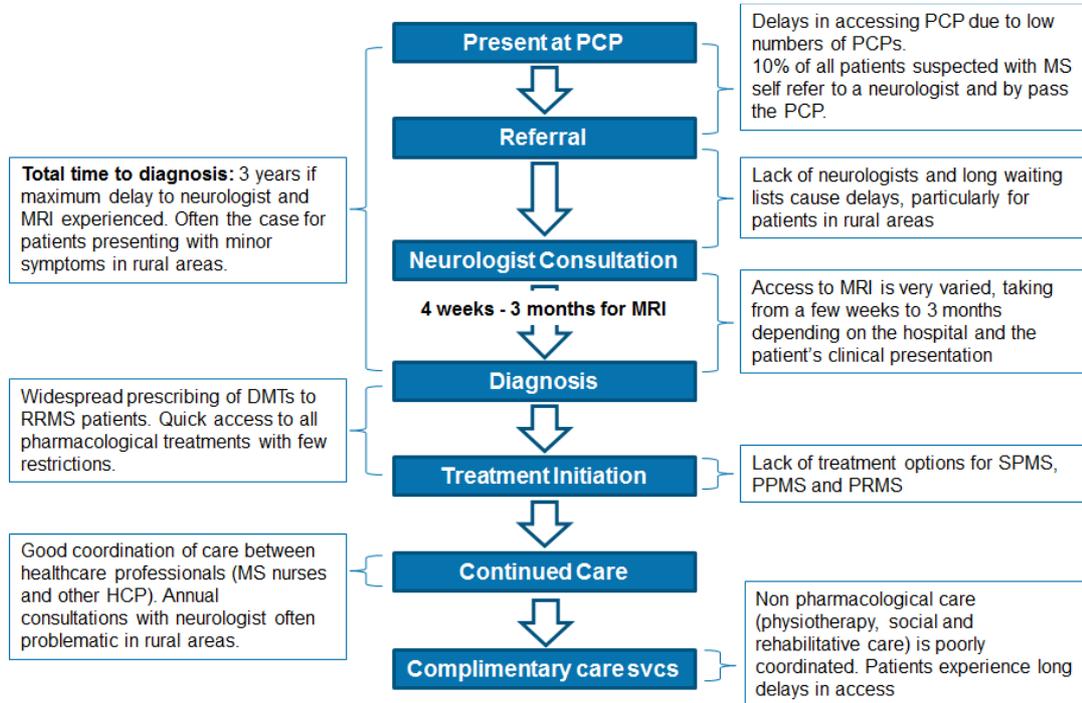
Source: CRA analysis

Drawing on the comparison in the last chapter, there are a number of areas where policy initiatives could improve patient access:

- Support development of infrastructure to enable patients in rural settings to access neurologists in a timely manner.
- Identify ways to facilitate and accelerate the Ministry of Health pricing and reimbursement process.
- Raise general awareness of MS in the population and amongst healthcare professionals to raise the quality of MS care across Spain.
- Investigate ways to encourage wider patient registry contribution from centres by addressing patient confidentiality concerns.

### 6.1.6. Sweden

Thanks to a relatively well funded healthcare system, there are relatively few barriers to access to MS treatment in Sweden. However, chronic lack of PCPs and neurologists in some areas create delays in getting a formal diagnosis. Once diagnosed, patients have access to relatively good care and to innovative treatments albeit with strict conditions. There are wide variations in access to care, and evidence on challenges associated with MS care in Sweden varied greatly from one respondent to another. The main challenges to access along the MS care pathway in Sweden are illustrated in Figure 13 below. These include the lack of coordination between health and social care; despite efforts to integrate them, this remains a distinct challenge for patients.

**Figure 13: Challenges to access along the MS care pathway – Sweden**

Source: CRA analysis

Drawing on the comparison in the last chapter, there are a number of areas where policy initiatives could improve patient access:

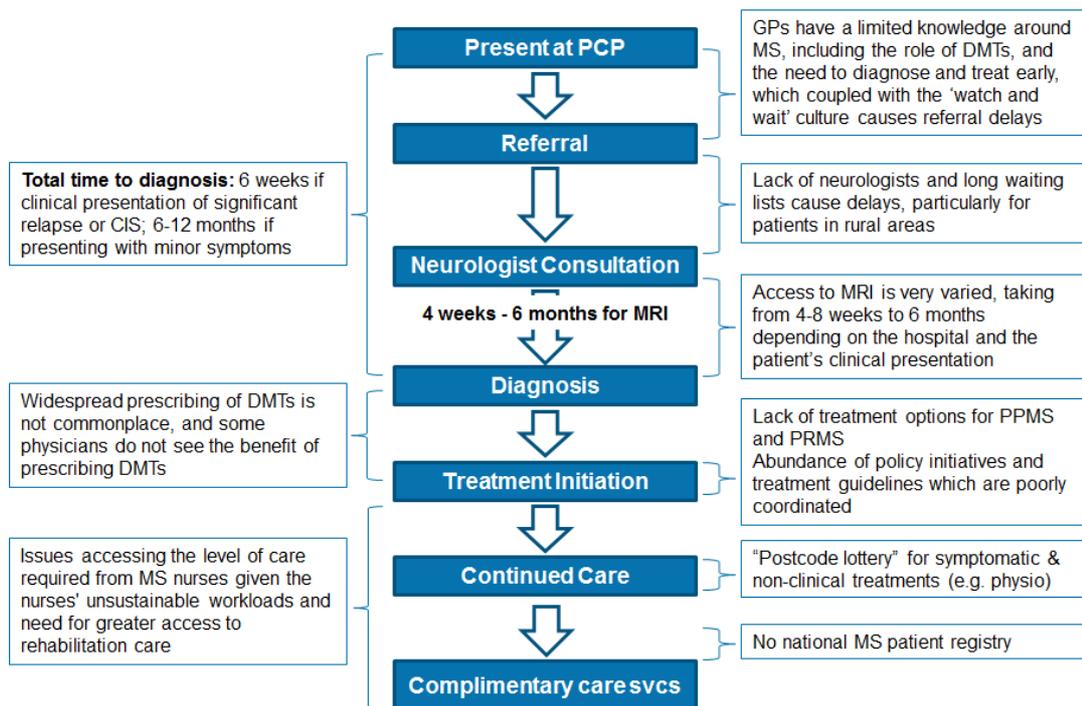
- Support development of infrastructure to enable patients in rural settings to be diagnosed in a timely manner.
- Raise the profile of MS, with the longer-term goal of increasing access to PCPs and neurologists (by increasing numbers).
- Investigate ways to clearly define the scope of healthcare and social care. Create incentives to social care providers to ensure service availability to MS patients.
- Support and encourage contributions from MS care providers to the MS registry in order to ensure that the information in these registries represents reality.

### 6.1.7. United Kingdom

Many of the 2014 MS report findings still apply to the UK. The delay in receiving a clear diagnosis was perceived to be one of the main barriers by healthcare professionals and other stakeholders in the UK, who recognised the importance of diagnosing MS rapidly and initiating treatment early but also acknowledged there are a number of hurdles to overcome in achieving this. Lack of awareness of MS symptoms by PCPs who are not sufficiently trained to recognise them certainly contributes this problem. Shortage of specialised neurologists and important variation in the time needed to receive an MRI are also important factors. Despite adequate coverage of MS treatment in the UK, patient access to DMDs is low. Whilst clinical guidelines

provide clear recommendations on the use of adequate treatment, respondents indicated some “patchiness” in neurologists’ knowledge of the available MS treatments, particularly the newer therapies; however the situation in the UK currently is beset by multiple documents around DMDs are developed separately and are often inconsistent. This exacerbate the variation in treatment across the healthcare system and leads to heterogeneous treatments pathways and prescribing practices. Another impact factor in access to care in the UK is the issues of “postcode lottery” in accessing care which means that the quality and availability of national health services you can expect depends on where you live. This create significant distortion in access to care such as the access to MS specialist centres and certain therapies which varies significantly by region. Once on treatment, despite an effective system of MS specialised nurses who effectively oversee a patient’s care, the lack of “comprehensive collaboration” between different healthcare units for MS has also been suggested as an important barrier to adequate patient follow-up. Finally, we observe that the UK still lacks a national MS patient registry to ensure adequate resource allocation and monitoring of the evolution of the disease burden. The main challenges to access along the MS care pathway in the UK, identified through the interviews, are illustrated in Figure 14: Challenges to access along the MS care pathway – United Kingdom below.

**Figure 14: Challenges to access along the MS care pathway – United Kingdom**



Source: CRA Analysis

Drawing on the comparison in the last chapter, there are a number of areas where policy initiatives could improve patient access:

- Raise public awareness of MS symptoms to tackle delays in PCP presentation.

- Educate PCPs on potential MS symptoms, available treatment options, and the need to diagnose and treat MS early to overcome the “watch and wait” culture.
- Raise the profile of neurological diseases, including MS, with the longer-term goal of increasing access to neurologists (increasing numbers and coverage).
- Increase investment in MRIs to address the lack of MRI units across the country.
- Leverage KOL network to dispel the myth – believed by some physicians – that DMDs do not benefit patients.
- Support the expansion of the MS nurse network to overcome workload issues and improve holistic care for all patients.
- Increase funding for non-clinical care such as physiotherapy/rehabilitation.
- Investigate ways to support the development of the patient registry.

## 6.2. Applicability of survey findings to the wider European setting

Drawing on the best practices highlighted above and some of the findings and conclusions from this survey, we were asked to assess the extent to which these conclusions are applicable in other countries and how these recommendations can be applied and leveraged by other healthcare systems.

To do this, we have developed high-level recommendations applicable to different country archetypes from the survey and considered if these are applicable for markets included in the first CRA study conducted in 2014<sup>234</sup> but which were not cases studies in this report (Austria, Belgium, Denmark, Finland, Italy, Norway, Romania & Slovenia).<sup>235</sup> We categorise those under the following groups:

- Western European countries social health insurance system (for example, Belgium, Austria)
- Nordic countries (for example, Denmark, Finland, Norway)
- Southern countries (for example, Italy)
- Central and Eastern European countries (for example, Romania, Slovenia)

### 6.2.1. Western European countries with social health insurance system

Drawing on countries with social health insurance based healthcare system and high levels of access such as Germany and France, similar countries (Austria and Belgium) are likely to have relatively few barriers to access to MS care at the early stage of the care pathway but most likely experience further hurdles further down the line of care. In both Germany and France

<sup>234</sup> Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Italy, Norway, Poland, Romania, Slovenia, Spain, Sweden, United Kingdom.

<sup>235</sup> These policy recommendations have not been tested with local policymakers or patient groups and are only intended as a starting point for a process of policy development.

patients are diagnosed relatively quickly thanks to a large decentralised network of GPs and specialised neurologists with a high level of freedom to prescribe and relatively few access conditions. As a result, initiation of treatment is also relatively swift and access to DMDs is adequate and timely. These countries however experience some challenges in ensuring the continuity of care treatment initiation. As in France and Germany, the highly decentralised and largely private provision of care often generates difficulties in ensuring adequate patient access to complementary care such as rehabilitation and palliative care which often lacks a clear focal point or reference person.

*Focus area for policy recommendations:*

Policymakers should focus upon:

- Accentuate effort on coordinated approach to care and continue to promote the development of MS network and ensure a more homogeneous coordination of all stakeholders involved in the care pathway across regions.
- Increase focus on rehabilitative care and ensure greater availability of neurological rehabilitation in rural areas.
- Support the expansion of the MS nurse network to overcome workload issues and improve holistic care for all patients.
- Increase funding for non-clinical care such as physiotherapy/rehabilitation.

### 6.2.2. Nordic countries

Although we have only considered the situation in Sweden, given that the health care systems in Nordic countries (Finland, Sweden, Denmark, Norway and Iceland) share some common characteristics (tax-based funding, largely publicly owned and operated hospitals, universal access based on residency, and comprehensive coverage) some of the recommendations are transferable.<sup>236</sup> Whilst the reality is considerably more complex, with great variation at the structural level in the way that institutions are designed, we assume that they experience comparatively few barriers to access to treatment. However, given the geographical nature of these countries and the population distribution, there are wide variations in access to care and the lack of PCPs and neurologists in some areas of the country is likely to be an issue across all Nordic countries. This often leads to complications in obtaining a formal diagnosis. However, given the relatively well funded healthcare system, patients have access to relatively good care when diagnosed and access innovative treatment is high. As in the western European countries, a lack of coordination between healthcare professional but also across the health and social care framework, remains a distinct challenge for patients despite efforts to integrate them.

*Focus area for policy recommendations:*

Policymakers should focus upon:

236

O.E.C.D. (2015). Health at a Glance 2015.

- Supporting the development of infrastructure to enable patients in rural settings to be diagnosed in a timely manner.
- Raise the profile of MS, with the longer-term goal of increasing access to PCPs and neurologists (by increasing numbers).
- Investigate ways to clearly define the scope of healthcare and social care. Create incentives to social care providers to ensure service availability to MS patients.
- Support and encourage contributions from MS care providers to the MS registry in order to ensure that the information in these registries represents reality.

### 6.2.3. Southern European countries

While they may embody similar principles of social policy organization to their northern European counterparts, southern countries share certain characteristics which distinguish them from other European countries. Both Spain and Italy have adopted National Health Services (similar to the UK) that is heavily decentralised at regional level. Other characteristics include the composition of healthcare costs, the role of private hospitals, and the entitlements of patients. The austerity-driven reforms in recent years have also had drastic effect on the provision of care leading to a reduction of public healthcare spending affecting parts of the healthcare system.

Drawing on our assessment of Spain, we suggest that access to MS care in southern countries such as is relatively well structured and there are few barriers at the early stage of the care pathway. Diagnosis and initiation of treatment is conducted reasonably quickly and this was not necessarily seen as a significant barrier. Once diagnosed, there are relatively few restrictions and limitations to accessing treatment, although access to treatment and care services can vary widely across regions. The Spanish health system like the Italian system is devolved, and each regions has its own responsibility for planning, provision and funding of care can lead to important variations in access to care across the country.

#### *Focus area for policy recommendations:*

Policymakers should focus upon:

- Support development of infrastructure to enable patients in rural settings to access neurologists in a timely manner.
- Continue to promote the development of MS network and or specialised MS centres to ensure a more homogeneous coordination of all stakeholders involved in the care pathway across regions.
- Raise general awareness of MS in the population and amongst healthcare professionals to raise the quality of MS care.

#### 6.2.4. Central and Eastern European countries

Whilst Central and Eastern European countries (CEEC) are in very different stages of economic transition, their health care systems are experiencing some similar challenges.<sup>237</sup> There are significant barriers to accessing the full continuum of care for MS patients in both Poland and the Czech Republic. However, this report has shown that both these countries face different sets of challenges. In general, CEECs are experiencing some level of social transformation and institutional changes which is putting pressure on public finances leaving funding below the levels of other European countries. This has resulted in a strict budget constraint on the healthcare system in both countries and has particularly affected diseases such as MS. Whereas Poland has imposed strict restrictions and access conditions across the entire MS care pathway, the Czech Republic has focused its restriction at the early stages of the care pathway (i.e. restrictions to enter into the system, and access to specialist and dedicated care centres). As CEECs continue to grow, it is likely that restrictions on access to new healthcare technologies and innovative treatments will increasingly be lifted. However, this is likely to lead to a new set of challenges such as those experienced by other European countries such as the interaction between healthcare and social care, the coordination of clinical professionals across multidisciplinary teams to deliver an integrated package of care and the need to address the geographical disparities in access to care with countries, all of which will become increasingly important.

##### *Focus area for policy recommendations:*

Policymakers should focus upon:

- Increase health care spending in line with economic growth and increase funding for MS to ensure greater patient coverage.
- Raise physician awareness of the need to diagnose and treat MS early to overcome barriers to fast neurologist consultation for non-emergency patients.
- Lower restrictions in access to treatment and expand treatment criteria to include all patients at early stage.
- Investigate ways to support the development of the patient registry and include measures of relative effectiveness of MS treatments.
- Continue to promote the development of MS networks and/or specialised MS centres to ensure a more homogeneous coordination of all stakeholders involved in the care pathway across regions.

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