

RETHINKINGMS

A policy assessment tool



Authorship

This project is led by the European Brain Council in collaboration with The Health Policy Partnership. For full details of funding and acknowledgements, please see page 22.

For more information on RETHINKING MS, please visit:

www.braincouncil.eu/RethinkingMS



CONTENTS

Foreword	4
Developing the policy assessment tool: methodology	6
National policy prioritisation	10
• Denmark	10
• Italy	13
• Romania	16
• Spain	18
Conclusion	21
Acknowledgements	22
Appendix I	
Summary of health systems and existing policies	24
Appendix II	
Attendees of country round tables	26
References	28



FOREWORD

One in three people in Europe will live with a brain disorder at some point during their life. Of these, neurodegenerative disorders such as multiple sclerosis (MS) pose particular challenges. The characteristics of these conditions – complex, evolving over time and requiring long-term care – demand a comprehensive approach to fully meet the needs of those affected.

MS affects more than 750,000 people in Europe, with consequences that extend well beyond the direct costs to health and social systems. A diagnosis of MS can be life altering, impacting almost every aspect of daily living for the person with MS and their family. Due to its early age of onset and unpredictable course, MS is associated with significant loss of quality of life, as well as work-related implications due to prolonged impairment and, potentially, reduced productivity. As MS is a degenerative condition, support for people with MS requires an integrated approach to health and social care that is personalised and adaptable.

In 2017, the European Brain Council published the Value of Treatment report, looking at key unmet needs in the care and support of people living with neurological conditions, including MS. The report highlighted the importance of implementing robust national strategies in every country, and strong engagement from stakeholders to identify policy gaps and priority areas for action. Ideally, these measures could, in time, be built into unified ‘national brain plans’.

Stemming from this work, the RETHINKING MS project was initiated in 2018 with a specific focus on MS, providing further insights into unmet needs and challenges experienced by people living with this complex disease. The findings have helped to clarify why we must rethink MS care in order to provide optimal treatment and support to all Europeans living with the condition.

A core goal of the RETHINKING MS project is to help drive tangible policy changes in the national context – *RETHINKING MS: a policy assessment tool* aims to support policymakers in that effort. Using the project's four profiled countries as models for the diverse national situations across Europe, the policy assessment tool seeks to demonstrate that every country, regardless of its starting point, has an opportunity to advance policy. While countries may all appear different, there are common challenges in managing MS and the proposals in this document may be adapted to fit a wide range of contexts.

We hope that this resource will prove a useful starting point for national-level stakeholders – policymakers, healthcare professionals and patient advocates – to work together to build evidence-based, locally relevant and sustainable policies. The nature of MS and other neurodegenerative disorders demands stronger health and social care in order to improve people's lives today and for the future.

Joke Jaarsma



'The nature of MS and other neurodegenerative disorders demands stronger health and social care in order to improve people's lives today and for the future.'



DEVELOPING THE POLICY ASSESSMENT TOOL: METHODOLOGY

The RETHINKING MS project involved several phases of research which led to a suite of reports. The *RETHINKING MS in Europe* policy report provided a pan-European policy analysis of unmet needs in MS and how best to address them. Four country profiles – *RETHINKING MS in Denmark, Italy, Romania and Spain* – were developed to provide an in-depth look at the MS-related policy, health and social care landscape in each country. These countries were selected in consultation with our Expert Advisory Group (EAG) to represent a broad range of national contexts from across Europe. An overview of key characteristics of the national health systems and policy landscape for MS in these four countries is presented in *Appendix I*.

RETHINKING MS: a policy assessment tool is the final resource of the RETHINKING MS project. It is intended as a starting point for the development of national MS policies, with the ultimate aim to build these measures into relevant national plans. This document presents priority areas for policy action, which were identified by consensus of national stakeholders as the most relevant and timely initiative to advance the care, support and quality of life for people living with MS in their respective countries. It is our hope that these priority areas will provide a useful basis for health authorities at both national and sub-national level in their ongoing policy and regulatory development efforts.

Please see the country profiles for Denmark, Italy, Romania and Spain for an in-depth analysis of access to timely diagnosis and use of personalised MS management strategies in these countries.

National stakeholder consultation

Local country leads were nominated from the EAG for the four profiled countries. With their support, round-table events were organised in the capital cities of Italy, Romania and Spain to discuss early drafts of the developing country profiles and identify priorities for policy change in each country. No round table was organised in Denmark; instead, the country lead from Denmark, an MS specialist neurologist, provided input into the prioritisation exercise in consultation with other leading MS experts and advocates in Denmark.

Process for the national round tables (in Italy, Romania and Spain)

The list of participants for each national round table was made based on recommendations from the country lead and other local EAG members. Regional and national health decision-makers, along with representatives from patient advocacy groups, neurology, nursing, rehabilitation, physiotherapy, occupational therapy, social care, general practice and other specialties, were invited to take part in the meetings. A list of the attendees for each round table can be found in *Appendix II*.

The round tables were structured to include presentations on:

- the RETHINKING MS project and overall project methodology
- preliminary findings of the country profiles based on expert interviews and desk research
- proposed priority gaps in MS care based on this research.

An international expert also presented on key MS policy challenges to highlight commonalities across Europe.

The floor was opened twice for general discussion, moderated by a representative from the national patient association: first, to provide feedback on the findings of the country profile, and second, for a more substantive discussion around the proposed priority area for action. The moderator aimed to identify consensus around one or more policy priorities which national stakeholders were interested to take forward after the launch of the RETHINKING MS project.

Outcomes from the round-table discussions in Italy, Romania and Spain, as well as the main recommendations emerging from the stakeholder consultation in Denmark, led to the identification of one key priority area for national policy development for each country. Summary recommendations as well as the four identified priorities are shown in *Figure 1*.

Completion of the policy prioritisation template

A prioritisation template (*Figure 2*) was developed to help identify ways in which the chosen national priority could be taken forward to become an effective policy or plan. This template was an adapted resource and had previously been used by ministries of health and European Union institutions to develop targeted national health plans for other therapeutic areas.^{1 2} It was presented to the EAG early in the project and validated in Italy, Romania and Spain with their national MS societies.

Following the round tables, each priority area was taken to the country leads and key national stakeholders for their detailed feedback. The country leads were asked to complete the policy prioritisation template; that input is summarised and discussed below in the section on 'National policy prioritisation'.

Figure 1. Key priority areas emerging from national stakeholder consultations. For Denmark, recommendations were determined from individual consultations; for Italy, Romania and Spain, these stemmed from round-table meetings.



Figure 2. Policy prioritisation template

Priority area	Selected priority to address
Goal	Statement of aims related to this priority area
Performance measures	Indicators and data sources to measure progress
Objectives	Objectives for goal that are specific, measurable, achievable, realistic and timely
Background	Rationale and evidence-base for the overall priority area and strategy
Activity	Chronological steps to be taken to achieve each objective
Timeline	Start and end date for each activity
Resources required	Resources needed for each action; examples include staff time, space needs, supplies, technology, equipment and key partners
Lead organisation	Key organisation to initiate the activity, provide direction for the work and monitor progress
Anticipated result	Direct, tangible and measurable results of the activity; examples include a policy, regulation, document, agreement or meeting
Alignment	Alignment between the national priority area and European priorities



NATIONAL POLICY PRIORITISATION



Denmark

Identified policy priority

Establish highly specialised, interdisciplinary and accredited MS centres

Context

Prevalence of MS

There are more than 16,000 people with MS in Denmark.³ However, the number of people with MS is increasing and has nearly doubled over the past 20 years.⁴ Denmark has the third highest incidence of MS worldwide.³

Background and rationale for chosen priority area

The management of MS is currently spread across 14 treatment centres varying in size, capacity, professional skill mix and treatment availability. One study estimates that at least 4,500 people with progressive MS have not seen a neurologist for more than one year,⁵ which may put them at risk of significant unmet care needs. With incidence rising, a reorganisation of treatment centres is needed to ensure a uniform interdisciplinary offering to people with MS across the country.

Currently, centres differ in the breadth of treatments available to manage MS. Smaller treatment centres may have fewer opportunities for professional knowledge sharing and development of best practice with respect to the wide variety of disease-modifying therapies (DMTs) that should be available for their patients. In addition, small patient numbers and high variability of symptoms may make it difficult for clinicians to gain experience in managing some MS symptoms.

European guidelines for the management of MS recommend that the full spectrum of DMTs be given only in centres with sufficient infrastructure, capable of offering a comprehensive monitoring of treatment effects and side effects.⁶ This is necessary to ensure appropriate management of side effects and efficacy monitoring.⁶ It is also important to ensure that the full range of symptomatic therapies is available in all centres to all people who might need them.

Proposed approach

To address the above challenges, it is proposed that highly specialised, interdisciplinary MS centres be established in each of Denmark's five regions. This restructuring of care will deliver more consistent treatment, increase knowledge sharing and strengthen the Danish MS research environment, ultimately creating a network for the study and development of new treatments. It will also improve efficiency of care by securing economies of scale and allowing for more optimal workflows. All this will help to ensure that more people with MS have a choice of effective DMTs and symptomatic therapies appropriate for their personal situation.

To create the five proposed regional centres, the smaller centres among the 14 existing MS treatment centres could:

- be merged with larger existing centres
- develop formal collaborations with larger existing centres
- become satellites of larger existing centres.

It is assumed that these reorganisations will be cost-neutral as this is a merger of current capacities. Furthermore, as digitisation is a hallmark of the Danish healthcare system,⁷ there should be limited logistical barriers to integration of and collaboration between centres.

Additional considerations

The rising number of people with MS in Denmark will pose challenges to the current workforce, as it will not be possible to recruit and train the required number of MS specialist neurologists in the near future. Instead, efforts should be focused on encouraging specialist training and education for nurses. If done over the next two years, this could secure enough MS specialist nurses equipped with the skills to take over certain tasks from neurologists, such as patient education.

Similarly, physiotherapists, occupational therapists and other relevant professionals should be trained to take over many of the scoring assessments that are part of regular MS monitoring and assessment. These include the Expanded Disability Status Scale (EDSS), Functional Systems Scores (FSS), Symbol Digit Modalities Test (SDMT), MS Functional Composite (MSFC), visual tests and gait tests.

Proposed priority initiative

Priority area	Establish highly specialised, interdisciplinary and accredited MS centres
Goal	Reorganise the care of people with MS into specialist centres to ensure an interdisciplinary, uniform offer throughout the country
Background	The Danish Healthcare Quality Programme was launched to further improve the quality of care, in line with overarching government goals in Denmark ⁸
Timeline	2020–2021
Activity	Establishing five specialised, interdisciplinary and accredited MS centres, either through merger of existing facilities or creation of new entities, with one centre per region
Performance measures	<ul style="list-style-type: none"> Establishment of five MS centres offering highly specialised, interdisciplinary and accredited treatment services with strong links to the Danish MS Association for psychological and social counselling assistance Appointment in an MS centre for every person with progressive MS who has not seen a neurologist for more than one year
Resources required	<ul style="list-style-type: none"> Human resources: specialist training for neurologists, nurses and other healthcare professionals in the coming years to meet the needs of a rising number of people with MS Funds: few additional resources required due to merging of existing resources and improved economies of scale
Lead organisation	Danish Multiple Sclerosis Center
Anticipated results	<ul style="list-style-type: none"> Increase in new patients: the centres will take 2,500 new people with progressive MS in the first year and an additional 2,000 the following year, and after two years all people with MS are being appropriately assessed⁹ Management of the approximately 80% of people with MS who will require an annual inpatient appointment, which by 2023 the five centres and satellites will handle without extra resources due to increased efficiencies compared to the 14 independent treatment sites⁹
Alignment	Integrated care models for chronic, long-term conditions is a key priority in Europe, both for inpatient and outpatient care



Identified policy priority

Develop integrated health and social care pathways for people with MS in all regions

Context

Prevalence of MS

In Italy, there are approximately 122,000 people living with MS and prevalence is increasing.¹⁰

Background and rationale for chosen priority area

The Italian National Health Service offers a network of specialised MS centres based in the neurological departments of certain Italian hospitals. In recent years, the Italian MS Society (AISM) has advocated for integrated care pathways ('Percorsi Diagnostici, Terapeutici e Assistenziali' or PDTAs) that would specify the range and standards of services that should be available within each region for all people with MS.¹¹⁻¹³ AISM is calling for these PDTAs to be implemented in each region and for a National Reference PDTA to be developed for MS, defining equal priorities for its management at the national level regardless of any regional differences. Additional recommendations include the establishment of a network of MS centres, an MS National Observatory Committee based at the Ministry of Health, the recognition of a National Disease Register and the inclusion of MS in the National Plan for Chronicity.¹⁴

Proposed approach

At the date of publication, PDTAs for MS have already been approved by 13 regional health authorities and are pending approval in 4 others.¹⁵ The goal would be to extend them to all 20 regions, and to integrate health and social services for MS following a specific plan for the disease which would be included in the National Plan for Chronicity.

The PDTAs would:

- clarify the rights of people with MS to receive appropriate care within their locality
- offer people with MS appropriately personalised treatment with DMTs
- ensure uniformity and harmonisation of treatment protocols across different regions and clinical centres
- integrate health and social services, facilitating collaboration among different healthcare professionals in MS centres and community settings
- ensure integration and data sharing between care pathways, health and social welfare systems
- further define rehabilitation needs across all phases of MS and improve access and the quality of rehabilitation services
- stratify people with MS into stages of disability progression and allow for the development of care and support programmes tailored to each stage
- promote engagement and empowerment of people with MS in the development, evaluation and implementation of care pathways
- define and apply a common indicators framework to measure both the outcomes, in terms of costs, processes and organisational factors, and the impact of care on the quality of life of people with MS.

Accordingly, AISM would work closely with the Ministry of Health and regional authorities to ensure MS is considered a priority in the next phase of review of the National Plan for Chronicity, in the revision of existing PDTAs and in the definition of future PDTAs for the remaining regions.

Additional considerations

None.

Proposed priority initiative

Priority area	Develop integrated health and social care pathways for people with MS in all regions
Goal	Ensure all regions have PDTAs providing fully integrated health and social care for all people with MS, and include MS in the National Plan for Chronicity
Background	The National Plan for Chronicity clarifies ambitions to provide person-centred and multidisciplinary approaches for all people with chronic diseases. ¹³ While the plan does not specifically refer to MS, it is still considered helpful in driving improvements in MS care
Timeline	2019–2020
Activity	Collaborating with the Ministry of Health and Regional Authorities to ensure that a plan dedicated to MS is included in the next review of the National Plan for Chronicity, working from the AISM model with the AISM's input
Performance measures	<ul style="list-style-type: none"> • Inclusion of MS in the list of prioritised illnesses in the National Plan for Chronicity • Implementation of an MS PDTA in every region • Full integration of health and social care services for people with MS, with services adapted to the complexity and degenerative nature of the condition and associated rehabilitation needs
Resources required	<ul style="list-style-type: none"> • Data analysis: AISM MS Barometer 2019¹⁰ and future iterations of the survey • Human resources: AISM national advocacy staff in close cooperation with regional AISM volunteer advocates • Priority links and connections: Italian Neurological Society and other professional societies; other patient and disability organisations • Funds: need to reallocate resources and integrate budgets that are currently spread between different agencies to avoid duplication and improve the efficiency of investment; for example, the health system, town councils' welfare budgets, funds for severe disability and the Italian National Social Security Agency (INPS)
Lead organisation	AISM
Anticipated results	<ul style="list-style-type: none"> • Inclusion of MS among prioritised chronic illnesses in the National Plan for Chronicity • Implementation of the National Plan for Chronicity at the regional level, with the inclusion of MS. This is being piloted in Piemonte in 2019
Alignment	Integrated health and social care for long-term conditions is a key priority in Europe



Romania

Identified policy priority

Ensure mandatory data collection for a national MS registry

Context

Prevalence of MS

In Romania, MS affects an estimated 9,000 people,¹⁶ of whom 5,000 were known to access the healthcare system in 2016.¹⁷

Background and rationale for chosen priority area

National registries are needed to facilitate a better understanding of the prevalence of MS, and the level and types of services required.

There are a number of policies and plans which call for the establishment of disease registries in Romania, but they have yet to be implemented. These include the National Strategy for Health 2014–2020,¹⁸ the National Strategy for Competitiveness 2014–2020,¹⁹ and an Emergency Decree (addition Article 6¹)²⁰ which describes the need to develop national disease registries that can be adopted and defined by specific governmental policies.

An MS registry was established by the Romanian Society of Neurology in 2013 in collaboration with the National Institute of Informatics using the iMED software system.²¹ However, uptake across the country is limited as participation is voluntary.

In 2017 the Ministry of Health, together with the Romanian Academy, initiated a project with European funding to create national disease registries for several high-priority conditions. For neurological diseases, MS was included alongside cerebrovascular disorders, epilepsy, dementia and Parkinson's disease. Although an official, national registry is still lacking, there have been many discussions regarding the development of an official MS registry.

Proposed approach

A comprehensive MS registry has been established but data collection must become mandatory and cover at least 75% of all people with MS in Romania, regardless of treatment status. This could be achieved with either:

- a new registry set up as part of the Romanian Academy project, which would ensure participation is mandatory
- the existing registry owned by the Romanian Neurological Society, mainstreamed and encouraged to be taken up among physicians.

Additional considerations

Integration of care and interoperability of healthcare services are high on the political agenda. In a letter sent to the Members of the Parliament in 2018, the Ministry of Health confirmed that several registries would be developed or updated to be interoperable, including one for MS.¹⁹ The development of national registries is also seen as an important part of the digitisation of care. The National Strategy for Competitiveness 2014–2020 contains several measures of digitisation of processes in different fields of government, including the health sector.

Proposed priority initiative

Priority area	Ensure mandatory data collection for a national MS registry
Goal	Guide improvements in the quality of healthcare and health status for each person living with MS through registry data
Background	<p>There are different policies and legislation which refer to the establishment of disease registries to improve the quality and efficiency of care. Along with the previously mentioned National Strategy for Health 2014–2020, the National Strategy for Competitiveness 2014–2020, the Emergency Decree (addition Article 6^{^1}), there is:</p> <ul style="list-style-type: none"> • Presidential Order nr. 245/2017 regarding the adoption of technical norms to roll out national curative health plans for 2017 and 2018 (extended to 2019)²² • Governmental Decision nr. 155/2017 regarding the adoption of national health plans for 2017 and 2018 (extended to 2019)²³
Timeline	2020–2021
Activity	<ul style="list-style-type: none"> • Designing a national MS registry or mainstreaming the existing one with the help of national authorities and the relevant national organisations involved in the treatment of MS • Launching public consultation about the functioning of the registry • Enshrining the registry's adoption and function in legislation
Performance measures	<ul style="list-style-type: none"> • Inclusion in the registry of all people with MS receiving DMTs and all cases diagnosed from 2020 onwards • Inclusion in the registry of at least 75% of all people with MS, regardless of type or treatment status • Full interoperability of the registry with other data collection systems
Resources required	<ul style="list-style-type: none"> • Human resources: training of clinicians, for example on inputting data and speaking to their patients about the registry • Priority links and connections: cooperation between relevant national agencies and organisations • Funds: financial support required
Lead organisation	<ul style="list-style-type: none"> • Ministry of Health • Romanian Neurological Society • Association of Patients with Neurodegenerative Conditions
Anticipated results	<ul style="list-style-type: none"> • Implementation of an Emergency Decree in the field of healthcare which refers to establishing disease registries • Integration of the registry into the project initiated by the Ministry of Health and the Romanian Academy, to preserve existing data and to formalise the obligation of data submission
Alignment	The European MS Platform is working to implement core data measures and quality standards, approved by the European Medicines Agency (EMA), in MS disease registries across Europe. ²⁴ EMA's Patient Registries' Initiative, launched in 2015, seeks to expand the use of patient registries in the European Economic Area ²⁵



Identified policy priority

Increase access to rehabilitation and social protection for people with MS

Context

Prevalence of MS

In Spain, the prevalence of MS is 100–125 cases per 100,000 inhabitants,²⁶ and the number of people living with MS is increasing.

Background and rationale for chosen priority area

Robust interdisciplinary care for people with MS includes full access to rehabilitation and psychosocial support.²⁷ Yet access to long-term rehabilitation is not covered by the Spanish health system. Rather, MS societies lead in providing rehabilitation, with partial funding frequently provided from social care budgets. Because of this, MS centres and neurologists are not coordinated with this important part of MS care and rehabilitation is not considered part of the health pathway. Mapping and improving the coordination of rehabilitation was identified as an important priority by Spain's National Health System Strategy on Neurodegenerative Diseases. This measure will help to ensure wider access to rehabilitation and increase the quality of life of people with MS.

An additional concern is that current disability assessments in Spain do not reflect the realities of MS. Disability is measured with several different scales and considerations,²⁸ and a minimum disability level of 33% is required to qualify for employment and support services and other related benefits. Yet the scales currently used to measure disability do not adequately measure invisible symptoms such as fatigue and depression, nor do they account for the progressive and unpredictable nature of MS. Furthermore, individuals conducting disability assessments may not always understand the nuances and challenges of the disease. These circumstances mean that disability scores assigned to people with MS are often undervalued.

As a result of this situation, people with MS face limitations in access to appropriate support services and social protection. Yet early access to social care support such as rehabilitation can be essential for the person with MS and their family to learn how to adapt to life with MS, and social care needs can increase suddenly due to the variability and unpredictability of MS symptoms and progression.

Proposed approach

In order to ensure that people with MS can have increased access to rehabilitation and social protection, appropriate resources must be allocated, and a consensus policy needs to be developed. This cohesive approach can then establish a frame of reference for effective translation into health policies at the national and regional levels. One specific strategy patient associations and clinicians are currently advocating for is to have people with MS automatically be assigned a 33% disability rating upon diagnosis.²⁹ This proposal must fit into the established National Health System Strategy on Neurodegenerative Diseases²⁶ and recommendations for the development of a national MS strategy.³⁰

Additional considerations

The National Health System Strategy on Neurodegenerative Diseases was adopted in 2016 for the management of diseases, such as MS, Alzheimer's and Parkinson's, with the aim of filling gaps and improving the quality of care of these complex and highly prevalent conditions.³¹ This strategy focuses on neurodegenerative diseases which raise common challenges in terms of management and have a high social impact, and are not included in other national health system strategies. In late 2019, the strategy for Alzheimer's was approved.³²

Although the National Health System Strategy on Neurodegenerative Diseases is a useful tool, it does not account for important differences between different neurodegenerative diseases in terms of their clinical evolution and impact on people's lives. For example, MS not only has significant economic and social implications, it is also extremely complex and can present in varying forms. Therefore, an individualised approach to MS is essential to ensure the specific needs of people affected are met. An ideal plan would expand on the recommendations in the National Health System Strategy on Neurodegenerative Diseases to further specify proposals for effective, personalised management of MS.

Healthcare funding and governance in Spain is shared between the Central Government and each of the 17 Autonomous Communities (ACs).³³ The Ministry of Health is responsible for authorising all pharmaceuticals, and sets reimbursement for most. It also sets the reimbursement for healthcare services, but provision of care and public health is decentralised to the ACs. Variations exist in priorities and health spending across the ACs,^{33 34} which may lead to differences in the implementation of any policy coming from the Central Government.

Proposed priority initiative

Priority area	Increase access to rehabilitation and social protection for people with MS
Goal	Improve the quality of life of people with MS through a real coordination of all the resources involved, both health and social, and develop an official policy to ensure appropriate long-term interdisciplinary care and social protection for people living with MS after their diagnosis
Background	The 2016 National Strategy for Neurodegenerative Diseases outlines ambitions for health and social care in MS, and is considered important in ensuring equal access to care. ²⁶ The <i>Recommendations for a national strategy on MS</i> report elaborates on the national strategy and outlines key actions to deliver its objectives ³¹
Timeline	2019–2020
Activity	<ul style="list-style-type: none"> • Meeting with the coordinator of the National Health System Strategy on Neurodegenerative Diseases to discuss the mapping exercise and official consensus protocol for coordination of the care pathway • Holding stakeholder meetings on mapping and consensus protocol led by the coordinator of the National Health System Strategy on Neurodegenerative Diseases • Arranging a workshop on social protection for chronic diseases led by the Ministry of Social Affairs
Performance measures	<ul style="list-style-type: none"> • Map of national and local social and health resources budgets • Increased allocation of resources towards implementation of the National Health System Strategy on Neurodegenerative Diseases • Development of a consensus protocol to ensure a better coordination pathway after diagnosis between the healthcare system and external services • Official designation of the above protocol as part of the National Health System Strategy on Neurodegenerative Diseases
Resources required	<ul style="list-style-type: none"> • Human resources: staff time and external support from consultancies • Priority links and connections: authorities' involvement
Lead organisation	<ul style="list-style-type: none"> • Esclerosis Múltiple España (Spanish MS Society) • Sociedad Española de Neurología (Spanish Neurological Society) • SEDENE – Sociedad Española de Enfermería Neurológica (Spanish Society of Neurological Nursing) • Sociedad Española de Farmacia Hospitalaria (Spanish Society of Hospital Pharmacists) • Plataforma de Organizaciones de Pacientes (Platform of Patient Organisations)
Anticipated results	<ul style="list-style-type: none"> • Improved and more coordinated access to social protection for people with MS, with implementation supported by official policies • Implementation of concrete action to strengthen integrated interdisciplinary care for people with MS
Alignment	Social protection for people living with MS and employment protection are key priorities in Europe



CONCLUSION

This policy assessment tool describes priority areas for the implementation of MS strategies based on input from national stakeholders from four different European contexts.

The priorities identified in Denmark, Italy, Romania and Spain stem from experts' consensus within those countries; however, they are also likely to also be relevant to other regions in Europe. Priorities are to:

- establish highly specialised, interdisciplinary and accredited MS centres
- develop integrated health and social care pathways for people with MS in all regions
- ensure mandatory data collection for a national MS registry
- increase access to rehabilitation and social protection for people with MS.

The ultimate aim is to build these priorities into a national policy planning exercise which would consider not just what has to be done, but who would need to be engaged to do so. Embedding proposed policies into national plans requires considered efforts to look at unmet needs, current care pathways and modes of service delivery and the daily needs of the people these policies aim to reach. Engagement from all relevant stakeholders is essential.

It is our hope that this document and other RETHINKING MS resources provide a useful starting point for such developments, both at a European and national level, and that they may contribute to improving the care of people living with MS across Europe.

We also hope that the policy analysis and prioritisation exercise undertaken as part of this project will serve as a useful template for work on other neurological conditions – ultimately forming part of comprehensive national brain plans in every country.



ACKNOWLEDGEMENTS

We would like to express our thanks to the members of the Expert Advisory Group who have provided guidance throughout the entire RETHINKING MS project:

- Professor Mario Alberto Battaglia, Italian Multiple Sclerosis Association and Italian Foundation for Multiple Sclerosis
- Professor Filippo Martinelli Boneschi, University of Milan and Neurology Unit Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico di Milano, Italy
- Pedro Carrascal, European Multiple Sclerosis Platform and Multiple Sclerosis Spain
- Iza Czarnecka, NeuroPositive Foundation, Poland
- Professor Jenny Freeman, University of Plymouth, UK; representative of Rehabilitation in Multiple Sclerosis (RIMS)
- Professor Kerstin Hellwig, St Josef Hospital, Bochum, Germany
- Anne Helme, MS International Federation
- Elisabeth Kasilingam, European Multiple Sclerosis Platform
- Professor Melinda Magyari, Danish Multiple Sclerosis Center
- Professor Maura Pugliatti, University of Ferrara, Italy
- Associate Professor Carmen Adella Sirbu, Dr Carol Davila Central Military Emergency Hospital, Neurology Clinic, Titu Maiorescu University, Romania
- Professor Per Soelberg Sørensen, Danish Multiple Sclerosis Center
- Professor Cristina Tiu, Carol Davila University of Medicine and Pharmacy, Romania
- Moira Tzitzika, Hellenic Federation of People with Multiple Sclerosis, National Rehabilitation Center, Athens, Greece
- Cristina Vlădău, Association of Patients with Neurodegenerative Conditions, Romania
- Donna Walsh, European Federation of Neurological Associations

With special thanks to Nicki Abel, MS specialist nurse and member of the Expert Advisory Group, who passed away before the completion of this project but whose insights were invaluable to the development of this project.

We would also like to recognise the high level of involvement of the country leads, who contributed significant time and expertise towards the development of this document:

- Professor Per Soelberg Sørensen, Danish Multiple Sclerosis Center
- Professor Mario Alberto Battaglia, Italian Multiple Sclerosis Association and Italian Foundation for Multiple Sclerosis
- Professor Cristina Tiu, Carol Davila University of Medicine and Pharmacy, Romania
- Cristina Vlădău, Association of Patients with Neurodegenerative Conditions, Romania
- Professor Ovidiu-Alexandru Băjenaru, Carol Davila University of Medicine and Pharmacy; Romanian Society of Neurology
- Pedro Carrascal, European Multiple Sclerosis Platform and Multiple Sclerosis Spain

About RETHINKING MS

RETHINKING MS is a research-driven project offering tangible policy changes to improve the lives of people living with MS across Europe, building on the 2017 Value of Treatment report from the European Brain Council. The RETHINKING MS series includes:

- *RETHINKING MS in Europe* – an analysis of unmet MS care and support needs across Europe, and sustainable policy recommendations to address them
- *RETHINKING MS in Denmark, Italy, Romania and Spain* – a series of reports providing an in-depth analysis of policy, care and support available for people with MS in each country.
- *RETHINKING MS: a policy assessment tool* – a resource showing how national priorities can be achieved in each country to have a real impact on the lives of people with MS.

Funding

The project is funded by Biogen, Celgene, Merck, Novartis and Sanofi. This project is supported by an Expert Advisory Group who have full editorial control and provide their time for free. Outputs aim to accurately represent a consensus from the Expert Advisory Group and are developed jointly between the European Brain Council and The Health Policy Partnership. All outputs are non-promotional and not specific to any particular treatment or therapy.

About the European Brain Council

The European Brain Council (EBC) is a non-profit organisation that aims to improve the lives of those living with brain disorders by advancing the understanding of the healthy and diseased brain through bringing together science and society.

About The Health Policy Partnership

The Health Policy Partnership (HPP) is an independent research consultancy, working with partners across the health spectrum to drive the policy and system changes that will improve people's health.

For more information on RETHINKING MS, please visit www.braincouncil.eu/RethinkingMS



APPENDIX I: SUMMARY OF HEALTH SYSTEMS AND EXISTING POLICIES

This table gives an overview of the priority countries' health systems and relevant existing policies.^{8 26 31 33 35-52} For more information, please refer to the country profiles.

	Denmark	Italy	Romania	Spain
National health system main characteristics	84% of healthcare expenditure publicly financed, 16% individual co-payments	Most health services free at the point of delivery but out-of-pocket spending on some therapies can be high	Public sources account for approximately 80% of health financing, many people face significant out-of-pocket costs	Most health services free at the point of delivery but out-of-pocket payments represent 24% of health expenditure
Health expenditure as % GDP	10.2% (highest country in OECD)	8.8% (OECD average)	4.9% (lowest EU country in OECD)	8.9% (OECD average)
Relative level of integrated care	Integration prominent, with a focus on information and communications technology	Variable levels of integration in different regions	Overall lack of integration between primary, hospital and public health	Variable levels of integration in different regions
Inclusion of MS in the national non-communicable disease or chronic disease plan	Yes	No	No	No
Existence of neurological disorders plan	No	No	Yes	Yes
Inclusion of MS in neurological disorders plan	N/A	N/A	Yes	Yes
Existence of national strategy on MS	Yes	No	No	No

	Denmark	Italy	Romania	Spain
National MS clinical guidelines	<p>Guidelines exist for treatment of MS. There are multiple historical guidelines, along with guidelines for physiotherapy and occupational therapy and for clinically isolated syndrome.</p> <p>The Medicine Council is also developing 'Joint regional treatment guidance for multiple sclerosis', and a new Specialist Committee for MS has been established to support this initiative</p>	<p>Percorsi Diagnostici, Terapeutici e Assistenziali or PDTAs are regionally specific guidelines for health and social care that incorporate recommendations from the Italian Society of Multiple Sclerosis (AISM) and guidelines from the Italian Neurological Society and European Committee for Treatment and Research in Multiple Sclerosis. National Reference Guidelines for PDTAs are currently under discussion among AISM, the Italian Neurological Society and Ministry of Health</p>	<p>A number of guidelines exist for the treatment of MS that have been updated in recent years by the Romanian Neurological Society</p>	<p>Consensus statement on the treatment of MS by the Spanish Society of Neurology in 2016 – incorporated by the National Health System Strategy on Neurodegenerative Diseases</p>
National MS registry	<p>Yes</p>	<p>A national Italian MS Register has been established by AISM and the Italian Federation of Multiple Sclerosis in conjunction with Bari University and MS centres, which is expanding data collection. There is also a regional register in Tuscany, which was the first officially recognised Italian MS register</p>	<p>A voluntary national registry organised by the Romanian Neurological Society</p>	<p>There are some regional and centre-level databases</p>



APPENDIX II: ATTENDEES OF COUNTRY ROUND TABLES

Italy

- Paolo Bandiera, Advocacy, Legal and General Affairs Director, Italian Multiple Sclerosis Society (AISM)
- Professor Mario Alberto Battaglia, President, AISM; Chairman, Italian Multiple Sclerosis Foundation (FISM)
- Dr Antonio Bertolotto, Head Physician and Neurologist, University Hospital San Luigi Gonzaga of Orbassano; Chairman, Piedmont Regional Committee for MS
- Dr Fabiola Bologna, Italian Member of Parliament; MS Specialist Neurologist
- Dr Giampaolo Brichetto, Director, MS Rehabilitation Centers of AISM; Researcher, FISM
- Dr Ovidio Brignoli, Vice President, National Society for Family Doctors (SIMG)
- Stefania Cappiello, President, Italian MS Nurses Society (SISM)
- Dr Salvatore Ferro, General Director, Department Hospital Services, Emilia-Romagna Regional Health Authority
- Professor Elisabeth Gulowsen Celius, Neurologist, Oslo University Hospital
- Dr Paolo Costantini, Medical Science Liaison – Neurology, Sanofi Genzyme
- Prof Claudio Gasperini, Neurologist and Director, MS Centre, Regional Hospital San Camillo-Forlanini, Rome
- Dr Chiara Gherardi, Government Affairs & Policy and Market Access Manager, Merck Serono SpA
- Professor Gianluigi Mancardi, Neurologist, University of Genova
- Professor Francesco Saverio Mennini, Research Director, Centre for Economic Evaluation and HTA, University of Rome Tor Vergata
- Christine Merkel, Senior Researcher, The Health Policy Partnership
- Dr Lucia Palmisano, Representative, Italian Ministry of Health
- Professor Francesco Patti, Neurologist, University of Catania
- Paola Pisanti, General Directorate of Health Planning
- Michela Ponzio, Coordinator of Public Health Research, AISM
- Professor Maura Pugliatti, Associate Professor of Neurology, University of Ferrara
- Vinciane Quoidbach, Research Project Manager, European Brain Council
- Professor Marco Salvetti, Neurologist, University of Rome
- Francesco Vacca, Board Member, AISM
- Dr Ketty Vaccaro, Director, Health and Welfare Area, Censis Foundation

Romania

- Andreea Antonovici, Association of Patients with Neurodegenerative Conditions (APAN)
- Frédéric Destrebecq, Executive Director, European Brain Council
- Silvia Dinulescu, APAN
- Roxana Giurca, MS Nurse, Elias University Emergency Hospital
- Christine Merkel, Senior Researcher, The Health Policy Partnership
- Dr Bogdan O Popescu, Neurologist, Colentina Hospital; President, Romanian Society of Neurology
- Vinciane Quoidbach, Research Project Manager, European Brain Council
- Associate Professor Carmen Adella Sirbu, Neurologist, Dr Carol Davila Central Military Emergency Hospital, Neurology Clinic, Titu Maiorescu University
- Professor Cristina Tiu, Neurologist, Carol Davila University of Medicine and Pharmacy
- Cristina Vlădău, Vice President, APAN

Spain

- Luz Caballero, Head of the Social Works Section, Hospital San Carlos
- Dr Miguel Ángel Calleja, Head of Hospital Pharmacy, University Hospital Virgen Macarena; President, Spanish Society of Hospital Pharmacists
- Mónica Escusa Campos, Corporate Communications and Patient Advocacy Manager, Biogen
- Pedro Carrascal, President, European MS Platform (EMSP); CEO, Multiple Sclerosis Spain (EME)
- Jesús Celada, Director of Disability Policies, Ministry of Health
- Miquel Díaz, Public Affairs, Multiple Sclerosis & Immunology, Sanofi Genzyme
- Dr Óscar Fernández, Neurologist, Regional University Hospital of Málaga
- Gabriela Hidalgo, Project Officer, EME
- Dr Yolanda Higuera, Neuropsychologist, Hospital Gregorio Marañón
- Manuel José Rancés Jofre, Secretary General, MS Association of Madrid; Spanish Association of MS (AEDEM-COCEMFE)
- María Jesús Miranda Maestre, Occupational Therapist, MS Society Aragon (FADEMA)
- David Elvira Martínez, Europe Public Affairs Head, Sanofi Genzyme MSOI
- Jimena Martinez-Pita, Government Affairs, Policy and Patients Advocacy Manager, Merck Group
- Christine Merkel, Senior Researcher, The Health Policy Partnership
- Jan Pachocki, Attorney-at-Law, Domański Zakrzewski Law Firm; Expert, Polish Brain Council
- Dr Guadalupe Piñeiro, Hospital Pharmacist, Álvaro Cunqueiro Hospital
- Vinciane Quoidbach, Research Project Manager, European Brain Council
- Dr Jaume Sastre-Garriga, Senior Consultant, Multiple Sclerosis Centre of Catalonia (Cemcat)
- Ana Torredemer, Board Member, MS International Federation
- José Luis Trejo, President, Spanish Brain Council
- Dr José Luís Trillo, Head of the Pharmacy Service of Primary Care, Department Valencia Clínico-Malvarrosa
- David Iglesias Villanueva, President, Spanish Society of Neurological Nursing; Nursing Supervisor, Hospital del Mar, Rome
- José Antonio Villanueva, Director, MS Society Navarra
- Catherine Whicher, Researcher, The Health Policy Partnership
- Dr Sergio Martínez Yélamos, Neurologist and MS Unit Coordinator, Hospital Universitario de Bellvitge; Coordinator, EMXarxa Care Network

REFERENCES

1. European Partnership for Action Against Cancer. National cancer plans. Available from: <http://www.epaac.eu/national-cancer-plans> [Accessed 20/11/19]
2. European Partnership for Rare Diseases National Plans Development. List of national plans. Available from: <http://www.euoplanproject.eu/NationalPlans?idMap=1> [Accessed 20/11/19]
3. Danish MS Society. 2018. Get all the numbers on sclerosis. Available from: <https://scleroseforeningen.dk/viden-og-nyt/hvad-er-sclerose/fa-alle-tallene-om-sclerose> [Accessed 16/01/19]
4. Magyari M, Sorensen PS. 2019. The changing course of multiple sclerosis: rising incidence, change in geographic distribution, disease course, and prognosis. *Curr Opin Neurol* 32(3): 320-26
5. Scleroseforeningen. Helhedsplan til 38,7 mio. kr. løfter scleroseområdet. [Updated 04/04/19]. Available from: <https://www.scleroseforeningen.dk/nyheder/helhedsplan-til-387-mio-kr-loeften-scleroseområdet> [Accessed 20/11/19]
6. Montalban X, Gold R, Thompson A, *et al.* 2018.ECTRIMS/EAN guideline on the pharmacological treatment of people with multiple sclerosis. *Eur J Neurol* 25(2): 215-37
7. Organisation for Economic Co-operation and Development. 2013. *OECD reviews of health care quality: Denmark*. Paris, France: OECD
8. Sundhedsstyrelsen. 2017. Healthcare in Denmark. Available from: https://www.sum.dk/~media/Filer%20-%20Publikationer_i_pdf/2016/Healthcare-in-dk-16-dec/Healthcare-english-V16-dec.ashx [Accessed 18/01/19]
9. Soelberg Sorensen P. 2019. Personal communication with Vinciane Quoidbach at the European Brain Council by email: 24/10/19
10. Associazione Italiana Sclerosi Multipla. 2019. *Barometro della Sclerosi Multipla*. Genova: AISM
11. Associazione Italiana Sclerosi Multipla. 2014. *Verso un percorso di presa in carico integrata della SM*. Genova: AISM
12. Gazzetta Ufficiale della Repubblica Italiana. Regulation for definition and implementation of national and regional hospital network and correlated organizational, technological and structural requirements. Available from: <https://www.gazzettaufficiale.it/eli/id/2015/06/04/15G00084/sg> [Accessed 02/12/19]
13. Ministero della Salute. 2016. *Piano Nazionale della Cronicità*. Rome: Ministero della Salute
14. Noto G, Raschetti R, Maggini M. 2011. *Gestione integrata e percorsi assistenziali*. Rome: Il Pensiero Scientifico Editore
15. Battaglia M. 2019. Personal communication by email with Christine Merkel and Catherine Whicher at The Health Policy Partnership: 22/10/19
16. Vladau C. 2019. Personal communication by email based upon 2018 data from The National Institute of Public Health: 19/11/19
17. Romania Adsmid. 2018. Împreună învingem SM. Available from: <http://sclerozamultipla.ro/> [Accessed 06/03/19]
18. Ministerul Sănătății. National strategy for health 2014-2020. Available from: <http://www.ms.ro/strategia-nationala-de-sanatate-2014-2020/> [Accessed 28/11/19]
19. Guvernul Romaniei. Programul operațional competitivitate 2014 – 2020. Available from: <http://www.fonduri-ue.ro/files/programe/COMPETITIVITATE/POC/Sinteza.POC.pdf> [Accessed 28/11/19]
20. Guvernul Romaniei. Emergency decree regarding the reglementation of certain measures in the field of healthcare. Available from: https://static.anaf.ro/static/10/Anaf/legislatie/OUG_8_2018.pdf [Accessed 28/11/19]
21. iMED. iMED homepage. Available from: <https://www.imed.org/en/home.html> [Accessed 22/11/19]
22. Guvernul Romaniei. Presidential Order nr. 245/2017 regarding the adoption of technical norms of roll-out of national curative health plans for 2017 and 2018. Available from: <http://www.cnas.ro/media/pageFiles/Ordin%20nr.245-Norme%20tehnice%20afere%20programelor%20na%20C5%A3ionale%20de%20s%20C4%83n%C4%83tate%20curative%20pentru%20anii%202017.pdf> [Accessed 28/11/19]

23. Guvernul Romaniei. Governmental Decision nr. 155/2017 regarding the adoption of national health plans for 2017 and 2018. Available from: <https://lege5.ro/Gratuit/ge2tkmbwguzq/hotararea-nr-155-2017-privind-aprobarea-programelor-nationale-de-sanatate-pentru-anii-2017-si-2018> [Accessed 28/11/19]
24. European Multiple Sclerosis Platform. MS Data Alliance in 2019. Available from: <http://www.emsp.org/news-messages/ms-data-alliance-in-2019/> [Accessed 27/11/19]
25. European Network of Centres for Pharmacoepidemiology and Pharmacovigilance. ENCePP Guide on Methodological Standards in Pharmacoepidemiology. Available from: http://www.encepp.eu/standards_and_guidances/methodologicalGuide4_3.shtml [Accessed 27/11/19]
26. Ministerio de Sanidad Servicios Sociales e Igualdad. 2016. *Estrategia en Enfermedades Neurodegenerativas del Sistema Nacional de Salud*. Madrid: Ministerio de Sanidad Servicios Sociales e Igualdad
27. Merck. 2018. *Sumemos: análisis y propuestas para contribuir a normalizar la vida con EM*. Madrid: Merck
28. European Multiple Sclerosis Platform. Spain claims the recognition of the 33 percent degree of disability for people with neurodegenerative diseases. Available from: <http://www.emsp.org/news-messages/spain-claims-the-recognition-of-the-33-percent-degree-of-disability-for-people-with-neurodegenerative-diseases/> [Accessed 20/11/19]
29. Federación Española para la Lucha contra la Esclerosis Múltiple. 2010. *Posicionamiento de FELEM y otras asociaciones de enfermedades neurodegenerativas ante la próxima reforma del Baremo y su adaptación a la norma C.I.F*. Madrid: FELEM
30. Fernandez O, Fernandez V, Guerrero M, *et al.* 2012. Multiple sclerosis prevalence in Malaga, Southern Spain estimated by the capture-recapture method. *Mult Scler* 18(3): 372-6
31. Palau F, March J, Trillo J, *et al.* 2018. *Recomendaciones para una Estrategia Nacional en Esclerosis Múltiple*. Madrid: Biogen
32. Government of Spain. Carcedo informa al Consejo de Ministros del Plan Nacional de Alzheimer 2019-2023. Available from: <https://www.mscbs.gob.es/gabinete/notasPrensa.do?id=4567> [Accessed 25/11/19]
33. Bernal-Delgado E, García-Armesto S, Oliva J, *et al.* 2018. Spain: Health System Review. *Health Syst Transit* 20(2): 1-179
34. Carrascal P. 2018. Interview with Christine Merkel at The Health Policy Partnership and Vinciane Quoidbach at the European Brain Council [Telephone]. 30/10/2018
35. Ferré F, de Belvis AG, Valerio L, *et al.* 2014. Italy: health system review. *Health Syst Transit* 16(4): 1-168
36. Organisation for Economic Co-operation and Development. 2017. *Spain: country health profile 2017*. Paris: OECD
37. Organisation for Economic Co-operation and Development. 2019. *OECD Economic Surveys: Denmark*. Paris: OECD Publishing
38. Organisation for Economic Co-operation and Development. 2017. Health spending. Available from: <https://data.oecd.org/healthres/health-spending.htm> [Accessed 4/02/2019]
39. Eurostat. 2019. Healthcare expenditure statistics. Available from: https://ec.europa.eu/eurostat/statistics-explained/index.php/Healthcare_expenditure_statistics#Developments_over_time [Accessed 04/11/19]
40. pro.medicin.dk. 2018. Multipel (dissemineret) sklerose. Available from: <http://pro.medicin.dk/Sygdomme/Sygdom/318380> [Accessed 10/07/19]
41. Radet for Anvendelse af Dyr Sygehusmedicin (RADS). 2016. *Behandlingsvejledning inklusiv lægemiddelrekommandation for sygdomsmodificerende behandling af multipel sklerose*. Copenhagen, Denmark: Radet for Anvendelse af Dyr Sygehusmedicin (RADS)
42. Sundhedsstyrelsen. 2015. *National Clinical Guideline for Physiotherapy and Occupational Therapy for Adults with Disabilities due to Multiple Sclerosis - 7 Selected Interventions*. Copenhagen, Denmark: Sundhedsstyrelsen


REFERENCES

43. Marziniak M, Ghorab K, Kozubski W, *et al.* 2016. Variations in multiple sclerosis practice within Europe - is it time for a new treatment guideline? *Mult Scler Relat Disord* 8: 35-44
44. Medicinrådet. 2018. Multipel sklerose: Medicinrådets vurdering af terapiområdet multipel sklerose. Available from: <https://medicinraadet.dk/igangvaerende-vurderinger/behandlingsvejledninger-under-udarbejdelse/multipel-sklerose> [Accessed 18/01/19]
45. Battaglia MA, Bandiera P, Ponzio M. 2019. Interview with Tommaso Manacorda at The Health Policy Partnership [Telephone]. 28/01/19
46. Associazione Italiana Sclerosi Multipla. 2018. *Barometro della Sclerosi Multipla 2018*. Genova: AISM
47. Bajenaru O, Tanasescu C, Tiu S, *et al.* 2010. Ghid de diagnostic și tratament în scleroza multiplă. Available from: <http://old.ms.ro/index.php?pag=181&pg=4> [Accessed 01/02/19]
48. Tiu C. 2019. Personal communication by email: 21/08/19
49. Cornea A, Rosca C, Simu M. 2015. The epidemiology of multiple sclerosis in Romania and across Central and Southeastern Europe - a historical review. *Romanian Journal of Neurology* XIV(3): 111-17
50. Garcia Merino A, Ramon Ara Callizo J, Fernandez Fernandez O, *et al.* 2017. Consensus statement on the treatment of multiple sclerosis by the Spanish Society of Neurology in 2016. *Neurologia* 32(2): 113-19
51. Glaser A, Stahmann A, Meissner T, *et al.* 2018. Multiple sclerosis registries in Europe - an updated mapping survey. *Mult Scler Relat Disord* 27: 171-78
52. European Commission. 2018. *Health system performance assessment - integrated care assessment study*. Brussels: European Commission



Rue d'Egmont, 11
BE-1000 Brussels
Belgium


Tel: + 32 (0) 2 513 27 57
info@braincouncil.eu

 @EU_Brain
www.braincouncil.eu

The
**Health Policy
Partnership**
[research, people, action]

68-69 St Martin's Lane
London WC2N 4JS
United Kingdom

Tel: + 44 (0) 20 3857 3643
info@hpolicy.com

 @HealthPolicyPtp
www.healthpolicypartnership.com