

EMSP Web Alert

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Citizens at the Centre of EU Health Policy

The Active Citizenship Network (ACN) organized on the 11-12th of April 2011 in Brussels the European Conference of the 5th European Patients' Rights Day to bring together different health stakeholders to discuss the real conditions of citizens in the health care services in Europe.

The first day focused on a reflection on the current situation of patients' rights. During the morning session, the second report of the ACN's project on "**Assessing Patients' rights in Europe**" was launched.

In 2002, ACN together with 15 citizen's organisations operating at national and European level drafted a European Charter of Patients' Rights. The main objective was to strengthen and bring greater awareness on patients' and citizens' rights. Three years later, ACN proposed a project to monitor the implementation of the Charter. A patients' rights matrix was established with indicators which collected and analysed information, assigned scores, identified critical elements and good practice and finally proposed an action plan.

The second report highlights that the **right of patients' time** (waiting time for diagnosis, treatment, specific exams...), the **right of free choice**, and the **right of access to care** are the least respected rights in the 20 countries participating to the project.

The Romanian EMSP Member (SSRM) participated to the ACN's project. Mrs Dudu shared with the audience the difficulties faced when gathering data and contacting relevant authorities and stakeholders such as hospitals. She confirmed that awareness on the rights to access should be raised in Europe.

The afternoon session – with opening remarks from the Commissioner Dalli – was dedicated to the best practices of civic participation in the field of health in Europe.



The second day focused on the presentation and discussion in plenary of proposed concrete actions by the participants and the presentation of the Directive on patients' rights to cross border healthcare seen by through the decision maker perspective (Antonya Parvanova, MEP), patients' perspective (Myeloma Euronet, Patient organisation) and the pharmacists perspective (Pharmaceutical group of the EU).

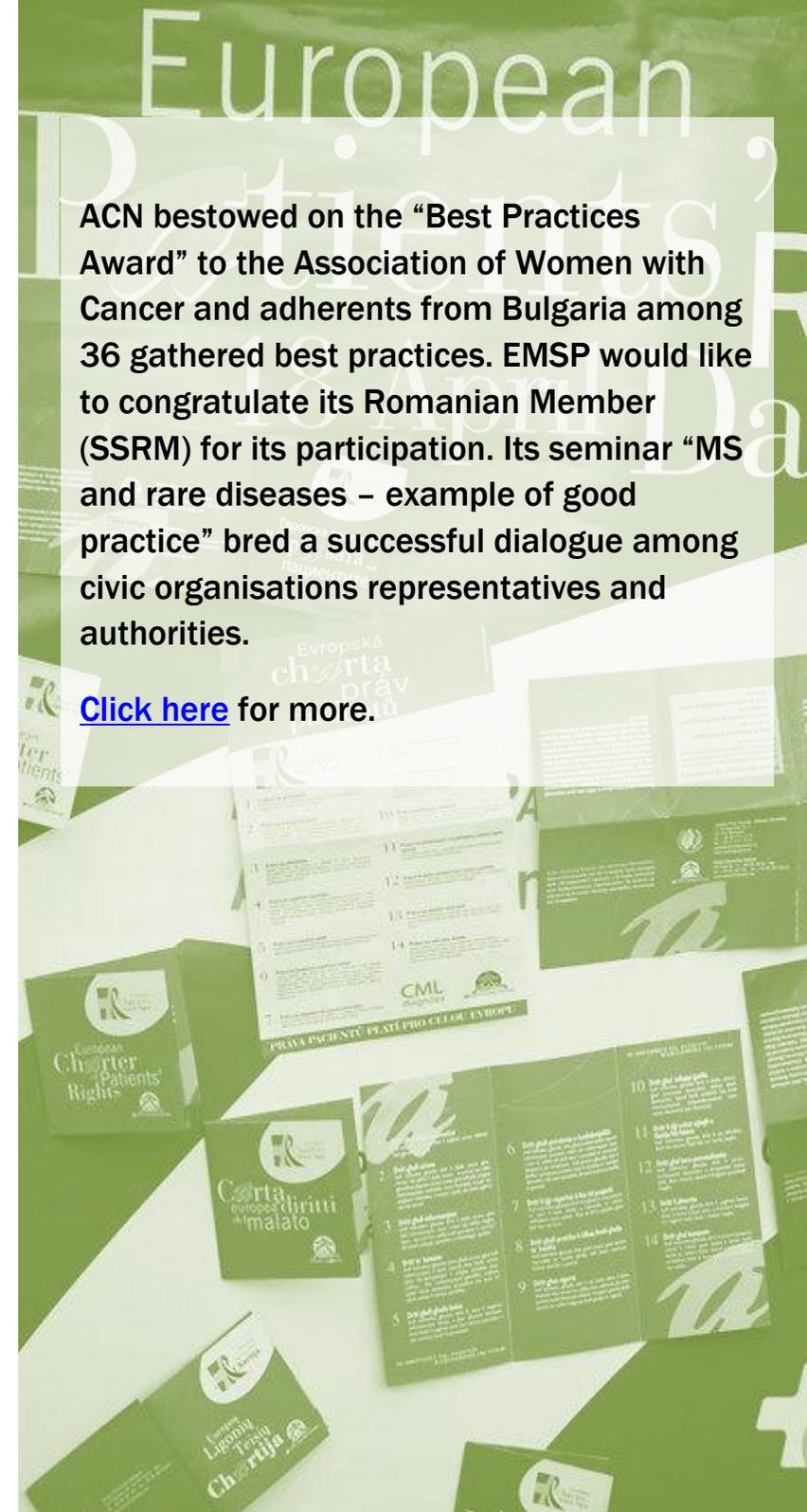
The Directive responds to a common objective: patients' rights must be equal all over Europe!

The key messages were the following:

- The Directive on Patients' Rights to cross-border healthcare DOES NOT encourage health tourism throughout Europe, but aims at **easing access for quality healthcare**.
- The Directive confirms a commitment to work for Patients' Rights and the beginning of a European Cooperation in terms of **European Standards for quality care and safety**.
- The Directive is only the **first step** in the right direction. It has to be transposed within national legislations to be effective; therefore, the actions should continue at local/national level for the recognition of the Patients' Rights.
- It is important to promote the European Charter for Patients' Rights, to work together to influence on-going policy decision-makers and **BE ACTIVE CITIZENS!**

ACN bestowed on the "Best Practices Award" to the Association of Women with Cancer and adherents from Bulgaria among 36 gathered best practices. EMSP would like to congratulate its Romanian Member (SSRM) for its participation. Its seminar "MS and rare diseases – example of good practice" bred a successful dialogue among civic organisations representatives and authorities.

[Click here](#) for more.



EPF Annual General Meeting

EMSP's participation at the Annual General Meeting of the European Patients' Forum (EPF) is an important opportunity to meet representatives of other patient organisations and discuss common issues, projects and policies. Julie Deléglise represented EMSP at the event (Brussels, 12-13 April 2011).

During the working dinner on the first day, participants discussed the specific capacity needs of both EPF and its members. This exploratory discussion will help the EPF develop its capacity building programme for national and European patient organisations. To better align its work with the needs and expectations of the young patient community, the EPF has developed a **Youth Strategy**. The evening also marked the first meeting of the **EPF Youth Group**, with Kristina Mäger from the Estonian MS Society (see following article) participating as the EMSP representative.

On the second day, EMSP followed the session on **Health Technology Assessment (HTA)**, an area in which the EPF has been working very proactively since the beginning of 2010. The session provided an opportunity for the EPF to share its first findings from a recently conducted survey to assess the current status of patient involvement in HTA in Europe. The report will be completed in July, and the results will be used to produce a tool to support patient organisations becoming actively involved in HTA processes. The session allowed participants to reflect on the next steps and brainstorm on the possible roles of the EPF and its members.

The following session examined the next **European Union Public Health Programme (2014-2020)** from the perspective of patients; attendees discussed the need for a campaign strategy with a particular focus on partnerships between patient organisations and industry. The session will feed into the EPF's position on the new Public Health Programme, and to a specific campaign to be organised jointly with other health organisations.

In the words of Kristina



In the photo: Kristina Mäger, a 24 year-old Estonian living with MS, served as the EMSP Youth Representative at the European Patients' Forum (EPF)

I was diagnosed in 2007: one day I woke up and saw everything double, and went straight to the hospital. That was a tough year. My child was just nine months old. Now, life has regained some normality: I am studying law and am on track to graduate this autumn. I previously worked at the Prosecutor's Office for three years, where I wrote documents that would be used at the courthouse or other juridical documents.

How did it feel to be selected as the EMSP Youth Representative at the EPF this year?

It was a great honour to be chosen – and a big responsibility! I did my best to collect all information that could be useful to help YPwMS understand their options and opportunities. Young patients are often confused when they are diagnosed, so it's important that they understand the many aspects of what it means to be a patient.

What did you do at the conference?

Not only did I learn about the functions and operations of the EPF, but I participated in several different sessions. Some of the topics were very specific, but in general, we discussed how best to solve problems that patients face on a daily basis. The whole thing was informative and inspiring.

The working dinner with the EPF Youth Group was great, too. Everybody was friendly, and it was interesting to hear the individual stories of each of youth representative and learn about their cultures. I met people of all ages and from all over Europe, many of whom I still keep in touch with by email or on Facebook. We did not discuss the depressing things – like what it means to be a patient, why this happened to us, and so on – we just had fun. I realised that all young people are full of energy and new ideas, and together we can do something great to improve the lives of young patients all over Europe.

What does the EPF Youth Group plan to do in the near future?

We are planning to create a Facebook group so that we can keep in touch and update each other on upcoming events. We also hope to meet again in Brussels this summer to discuss how to put our ideas into practice. I have great expectations for the EPF Youth Group: our team is fantastic and full of ideas, and I hope we can make a real difference in improving the lives of patients.

I hope I represented young people with MS as good as possible and I'm hoping to make a good contribution in future in our EPF Youth Group to improve people with MS' lives.

On 15 April 2011 the European Medicines Agency held a stakeholder forum on the implementation of the new pharmacovigilance legislation with a broad cross-section of participants including industry, patient and healthcare professional representatives and national medicines regulatory authorities. This was the first in a series of stakeholder meetings taking place during 2011 and 2012, when the Agency aims to raise awareness of the requirements of the new legislation and promote the exchange of ideas, concerns and opinions.

During this first meeting, immediate feedback from stakeholders was received mainly in relation to the Agency's and Member States' technical contribution to draft European Commission implementing measures. Close co-ordination and co-operation with stakeholders will maximise the opportunities for a successful and efficient adoption of new requirements, which come into legal force in July 2012.

The discussions during the day highlighted several key aspects of the new legislation including:

- changes to inspections and pharmacovigilance systems including the introduction of Pharmacovigilance System Master Files;
- use of internationally agreed terminology, formats and standards for the performance of pharmacovigilance activities;
- minimum requirements for monitoring data in EudraVigilance;
- changes to Periodic Safety Update Reports (PSURs);
- format and content of risk management plans;
- new measures for transparency and communication including the creation of websites to highlight safety issues with medicines and the introduction of a public hearing process.

All presentations from the stakeholder forum have been published (www.ema.europa.eu).

A second stakeholder forum will be held on 17 June 2011. Participants will include representation from similar groups to those present at the first meeting, and will be invited by the Agency as appropriate once agenda topics for the day have been finalised.

The new pharmacovigilance legislation, which amends existing legislation, was adopted in the European Union in December 2010. The legislation aims to save lives by strengthening the European-wide system for monitoring the safety of medicines. The new legislation forms part of a three-piece 'pharmaceutical package' and amends existing pharmacovigilance legislation contained in Directive 2001/83/EC and Regulation (EC) No. 726/2004. The remaining parts concerning falsified medicines and information to patients have not yet been adopted by the European Parliament and the European Council.



First stakeholder forum on the implementation of the new pharmacovigilance legislation

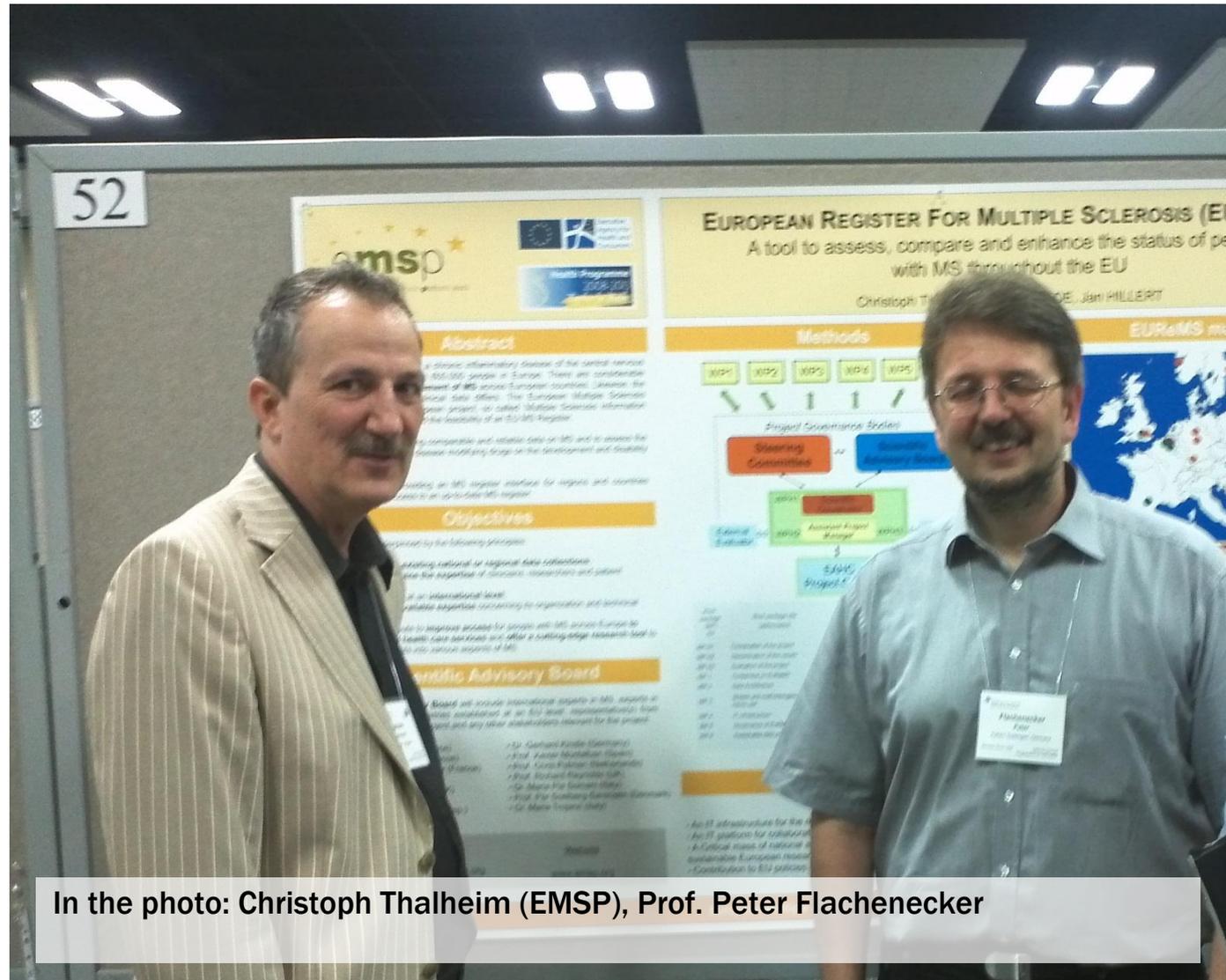
EMSP presents EUREMS project at American Academy of Neurology Congress 2011

European Register for Multiple Sclerosis (EUREMS), EMSP's biggest project ever, was presented at the American Academy of Neurology Congress (Honolulu, 10-16 April 2011). Christoph Thalheim, EMSP Secretary General, took advantage of this great opportunity to raise awareness among a truly international audience - AAN this year attracted more than 10 000 neurology experts. The project received strong interest from both neurologists and patient advocates from all over the world.

EUREMS is unique for building a core dataset that combines medical and socio-economic patient data.

EMSP regards this synthesis as the optimal way forward as it supports scientific research as well as patient advocacy for better quality of life. Representatives from the United States and Canada expressed their hope to each build a similar register in their countries, and congratulated the Europeans for being the first to develop such a useful (and badly needed) cross-border endeavour. Delegates from Latin America, where a few countries already have national MS registers, showed interest in following the development of EUREMS for inspiration for a future MS register that covers the entire region and asked for advice on how to set up a platform similar to EMSP for MS patient organisations in Latin America.

For more information about the project please visit: www.emsp.org



In the photo: Christoph Thalheim (EMSP), Prof. Peter Flachenecker

An international professional conference was held in Pécs, Hungary in March for civilians with the participation of MS organizations from ten CEE countries. The event organized by the Foundation for Hungarian Patients With Multiple Sclerosis (Hungarian abbreviation MSMBA) aimed at serving as an opportunity for exchange of experience concerning the patient organizations' work exercised for the MS patients of the region, sharing the plans and results achieved in the treatment and rehabilitation of MS patients, as well as presenting and discussing good practices.

In parallel with the conference entitled **Past and Future - Conference in the Mirror of the European MS Movement** and realized with the support of the Visegrad Fund there was also a neurological conference taking place in Pécs with the participation and active involvement of the most renowned experts of the world. The participants of the two events could have the opportunity to meet each other at a common social program organized at a traditional Hungarian 'csarda'. The conference of the civilians was also furthered and supported by the Hungarian Government through the attendance of its representatives. The event attracted significant press interest: several media reported about the conference and the aims and objectives of MS patients.

The event was organized by the biggest Hungarian MS foundation that has done a lot in the past decade so that Hungarian patients could get access to the therapies necessary for the improvement of their life expectancy. It is the foundation that operates the one and only MS Rehabilitation Centre in Nyíregyháza specifically serving the needs of MS patients. The further improvement of this centre and making it suitable for accommodating the patients belong to the highest priorities of the civilians working for Hungarian MS patients.



The patient organizations have reported on the results and concerns related to rehabilitation in their countries. There is an important lesson to highlight: it does matter where a patient was born; there are huge differences as far as the accessibility

Rehabilitation and co-operation: the representatives of ten countries in Hungary

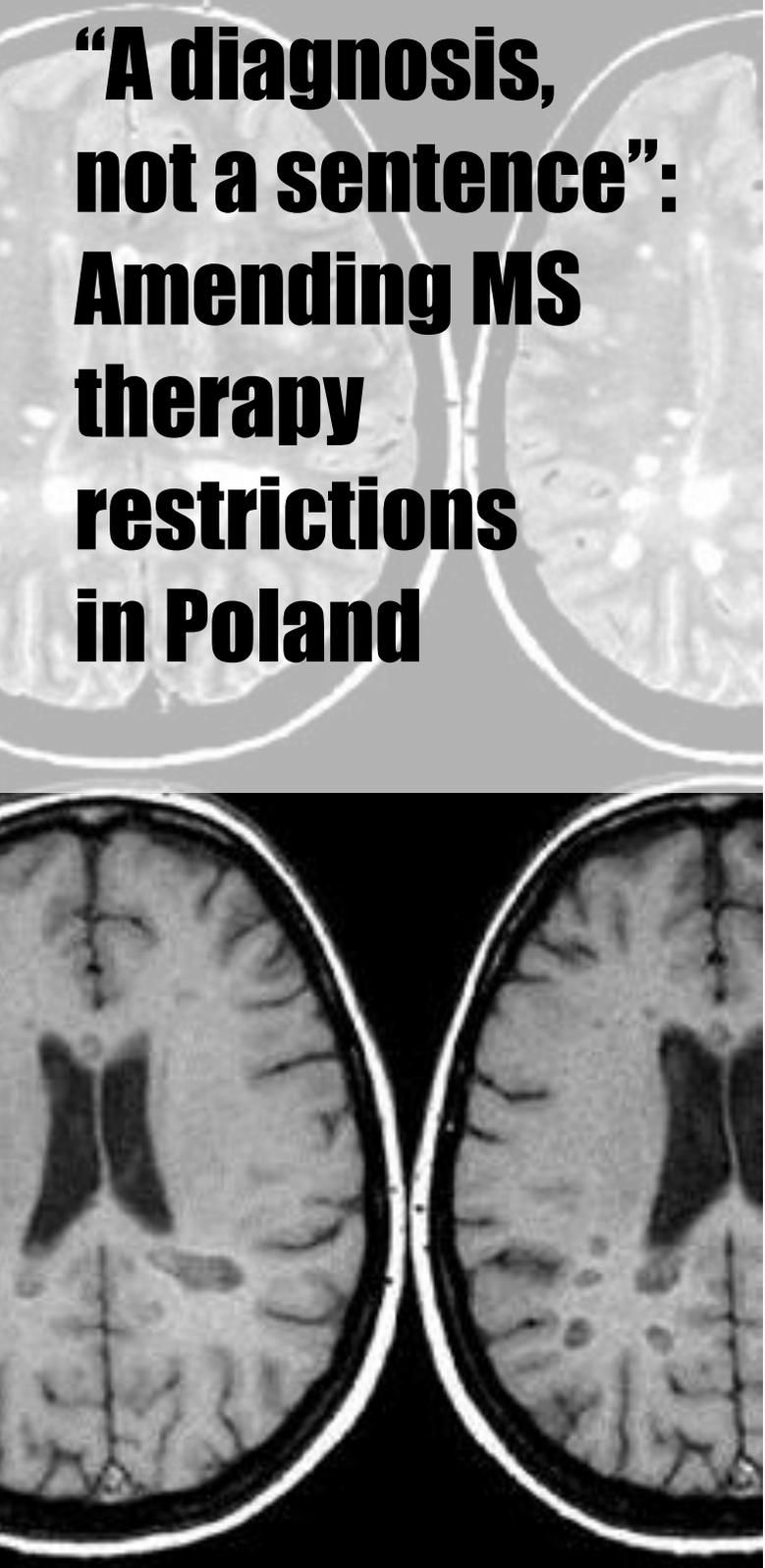


of MS pharmaceutical therapy, rehabilitation and labour market related opportunities are concerned. For example, while in certain countries even the most basic pharmaceuticals or physiotherapeutic treatments are out of reach, elsewhere the treatment tries to deal with the mental and psychic care of the patients as well, and it is also a significant aspect to help improving even the patients' quality of life.



At the conference the delegates of the European MS Platform were also present and introduced the comprehensive European MS data collection and analysis system to be launched in 2011, the structure of the EUREMS project and also the expected results. The event gave a good opportunity for the representatives of patient organizations and also the participating MS patients for an exchange of their professional views, as well as for strengthening international relations and co-operations.





“A diagnosis, not a sentence”: Amending MS therapy restrictions in Poland

Polish MS Society (PTSR) moved a big step closer to ensuring greater equality in access to therapy for all people with MS, in part by holding a press conference to denounce discriminatory health policies.

Due to budgetary constraints, in 2004 Polish authorities began to limit the duration of MS therapy using disease-modifying drugs (DMDs) to a maximum of two years and later to three years for a given patient. The policy also contained discriminatory age conditions, stating that only PwMS between 16 and 40 years of age could qualify for the therapy.

The PTSR took action against these restrictions, which denied PwMS from having equal access to therapy programmes and the same chances for improved quality of life. In June 2010, the PTSR submitted a proposal to the Ministry of Health to abolish these restrictions; Polish neurology experts and EMSP supported the proposal.

Nine months later, nothing had changed; despite many promises, PwMS were still in the same situation. The PTSR thus held a press conference (Warsaw, 31 March 2011) in the Polish Press Agency headquarters, dedicated to amending the restrictive MS therapy regulations.

The day before the conference, Vice Minister of Health Adam Fronczak was informed that the Minister of Health, Ewa Kopacz, had accepted two new MS therapy programmes. The first reflected changes proposed by the PTSR, the most important of which were reducing the qualification criteria for therapy and removing the discriminative age limits. The second programme accepted by the Ministry concerns the possibility of using natalizumab (monoclonal antibody) as the second line of MS treatment.

During the conference, Prof. Krzysztof Selmaj, Chairman of the PTSR Scientific Advisory Board, presented the negative consequences of discontinuing DMD therapy after only three years. Because DMD therapy is preventive, it should be started shortly after diagnosis and continued as long as it delivers therapeutic results. He also compared Polish MS therapy regulations with European standards: although access to DMD therapy in Poland is increasing, at present, only 8% of PwMS who would benefit have access to it. The EU average is 30%.

The acceptance and amendment of these programmes by the Ministry of Health is an important step toward fair access to treatment for PwMS, and the PTSR and EMSP are pleased with this progress. However, both programmes still need to be evaluated by the Agency of Medical Technology Assessment (AOTM); only after its approval will the programmes be implemented.