

EMSP Web Alert

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An important step forward for all patients in the European Union



The [Directive on the application of Patients' Rights in Cross-border Healthcare](#) creates a clear and transparent legal framework within the European Union. The Council of the European Union approved the Directive on the 28, February 2011. The overall aim of the Directive is to ensure that patients can access safe, efficient and good quality treatment in a Member State other than their Member State of affiliation, and to be reimbursed for it.

How does this Directive benefit citizens?

Uncertainty about the general application of rights to reimbursement for healthcare provided in other Member States is creating obstacles to the free movement of patients and, more generally, of the provision of health services in practice. By clarifying the rules to be applied for the reimbursement of healthcare provided in other Member States, this Directive will facilitate the access and provision of cross-border healthcare.

This Directive states that patients will be reimbursed the same amount that they would receive in their Member State of affiliation for the same type of healthcare. An important aspect is that if the Member State of affiliation does not include a particular treatment as part of the entitlement for their citizens at home, this Directive does not create any new entitlement for patients to be reimbursed for such treatment abroad.

National Contact Points

Member States will be required to establish National Contact Points to provide patients with clear, accessible and reliable information. These centres will exchange information among them and provide practical information to patients on conditions and levels of reimbursement, possible treatments and providers.

Continuity of care and recognition of prescriptions issued in another Member State

Provision of medicinal products will often be part of cross-border healthcare and may form part of an on-going treatment protocol that should continue to be applied in the patient's home country.

To ensure continuity of care, the Directive includes several measures:

- The country of treatment will guarantee that patients have access to written or electronic medical records related to the treatment they received;
- The country of affiliation will ensure the medical follow-up is of the same quality, regardless of where in the European Union the initial treatment was provided; and
- Prescriptions issued abroad must be recognised, though whether the medication is reimbursed remains the prerogative of the affiliated Member State.

European Reference Networks and Health Technology Assessment

The Directive supports the development of European Reference Networks to create stronger links, on a voluntary basis, among specialised centres of expertise already recognised in Europe. Such collaboration has great potential to benefit patients by providing easier access to highly specialised care and health systems, and by pooling resources to tackle rare conditions.

Likewise, Member States will facilitate the development and functioning of a network connecting the national authorities or bodies responsible for Health Technology Assessment (HTA). This network aims to support provision of objective, reliable, timely, transparent and transferable information regarding the short- and long-term effectiveness of health technologies. It will also enable an effective exchange of this information among national authorities or bodies.

Establishing such networks will also help the medical market within Europe to realise its potential by maximising the speed and scale of diffusion of innovations in medical science and health technologies. By promoting the highest possible quality of care, these networks will transfer numerous benefits to both patients and healthcare systems.

The cost of cross-border care in the total public health budget

The European Commission estimates that 1% of the public healthcare budget is spent on cross-border healthcare (including emergency care), which currently totals approximately EUR 10 billion. This relatively small scale is unsurprising, as people prefer to have healthcare as close to home as possible.



E-health

Information and communication technologies have enormous potential to improve the quality, safety and efficiency of care. Member States will promote the cooperation and exchange of information via a voluntary network: the e-Health network.

Advancing from EU Directive to national policy

After formal adoption by the Council of the European Union, the Directive shall enter into force on the twentieth day following its publication in the *Official Journal of the European Union*. National governments then have 30 months to integrate these measures into national legislation.

Further steps:

Member states will have 30 months to transpose the Directive's provision into national legislation.



EU Clinical Trials Registry goes live



The EU Clinical Trials Register (www.clinicaltrialsregister.eu) was launched on the 22nd March 2011 by the European Medicines Agency. The online register gives for the first time public access to information on interventional clinical trials for medicines authorised in the 27 EU Member States and Iceland, Liechtenstein and Norway. The database also allows the public to search for information on clinical trials authorised to be carried out outside the EU if these trials are part of a paediatric investigation plan.

The information contained in the EU Clinical Trials Register is extracted from EudraCT, the EU clinical trials database. It is provided by the sponsor of the clinical trial, and is a component of its application to a national medicines regulatory authority for authorisation to conduct a trial. The information from the sponsor is loaded into the EudraCT database by the national medicines regulatory authority. The authority adds to this information the authorisation of the clinical trial and the opinion from the relevant ethics committee. Information on third country trials that are listed in a Paediatric Investigation Plan (PIP) is provided by the PIP addressee directly, via the EMA, to the system.

Throughout the project the Agency worked together with stakeholders, including patients and healthcare professionals, to ensure that their needs were taken into account, to the extent possible at this stage, when designing the register.

Lise Murphy, co-chair of the Agency's Working Party with Patients' and Consumers' Organisations said: 'we welcome the launch of the EU Clinical Trials Register. It increases transparency of medical research and will make it much easier for patients to find information about clinical trials taking place in Europe. We are committed to continue working with the EMA to further develop the system so that it becomes a valuable and useful resource for patients across the EU.'

The Agency will continue to work with stakeholders to improve the functioning of the EU Clinical Trials Register, in particular by enhancing the quality and completeness of data, and improving the search functionality. Plans for the future also include the publication of summaries of clinical trial results, on which draft guidance has already been published for consultation by the European Commission. Publication of trial results summaries will require a major upgrade to the existing system, the start of which will depend on finalisation of the guideline and availability of budget and resources.

For more information about the EU Clinical Trials Register, please contact Monika Benstetter or Sabine Haubenreisser at press@ema.europa.eu

Improving patient protection from falsified medicines

The European Commission estimated that 1% of medical products currently sold in the European Union through the legal supply chain are falsified – and that the figure is growing. Since 2005, seizures of counterfeit medicines have soared by 400%.

The [Directive on prevention of the entry into the legal supply chain of counterfeit medical products](#), amending Directive 2001/83, was adopted by the European Parliament on 16 February 2011. This Directive is expected to improve patient protection and strengthen the European system by closely monitoring safety. However, it will enter into force after being formally adopted by the Council of the European Union.

The Directive comprises the following elements:

Safety features, traceability and product recalls

As a general rule, safety features (to be developed by the European Commission) would apply to all prescription medicines excepting those not considered as being at risk of falsification. The use of a unique identifier will enable pharmacists to check each pack for authenticity before dispensing products to the patient.

The Directive states that if a medicinal product is suspected to present a serious risk to public health, all actors in the supply chain – in all Member States – must be alerted quickly. If the suspected medicine may have already reached patients, an alert to recall the product must be given within 24 hours.

Internet sales

Strict regulation of the sale of medicine on the Internet is critical, as this is a key route by which counterfeit products enter the EU market. Internet pharmacies in EU Member States will need to be authorised to supply pharmaceuticals to the public, and will also be required to display a common logo, recognisable throughout the European Union, so as to help the public to ascertain that they are linked to an authorised pharmacy. Member States must set up national websites with information about online sales and authorised Internet pharmacies, as well as the risks of buying medicines online. These sites will be linked to the European Medicines Agency website. The Directive aims to raise public awareness of the dangers of false medicines, including the risks of Internet sales.

Further steps

This Directive shall enter into force on the twentieth day following its publication in *the Official Journal of the European Union*. National governments will have 30 months to integrate these measures into their national legislation.

World MS Day 2011 will take place on the 25th May this year. In 2011 the focus is on 'Work and MS'.

World MS Day will see organisations and individuals from more than 85 countries coming together to create awareness about MS and advocate for positive change. They will highlight the simple and cost-effective changes that employers can make in the workplace. These changes can enable people with MS to stay in work for longer, giving them the opportunity to continue to contribute to their family income, to their communities, and to the economy.

To get involved contact your national MS society or go to www.worldmsday.org to find out more.

For more information on the World MS Day 2011, please contact Ayesha Ali at ayesha@msif.org

World MS Day



In the Photo:
Lori Schneider on mount Everest
summit with World MS day flag
Web: www.ETAdventure.com

European Voluntary Service

MS Society of Romania benefits from EVS, says
Claudia Torje, CEO

What was the mission of your EVS volunteers?

Volunteers participated in activities with patients from the local MS organisation in Oradea, but also in other Oradean organisations for persons with disabilities.

Where did the volunteers come from?

Volunteers were from France, Spain and Germany and stayed in Romania for six months.

What costs did your MS Society incur?

We covered 10% of the transport costs. Accommodation, meals, transportation, Romanian language lessons and a volunteer's allowance were provided by the European Commission through the Youth in Action Programme.

Do you want to host more volunteers via the European Voluntary Service?

Of course! We are in the process of filing a new EVS Expression of Interest form. We hope to host new volunteers by the end of 2011.

The European Voluntary Service (EVS) enables young people (18 to 30 years old) to carry out voluntary service for up to 12 months in a country other than their country of residence.

EVS activities

The EVS spans a wide range of areas such as culture, youth, sports, social care, culture heritage, the arts, civil protection, the environment and development co-operation. But all activities must be not-for-profit. EVS activities can be carried out either individually or as a group: up to 30 volunteers can participate in a single EVS project.

Benefits of the EVS

Volunteering through the EVS provides young people with an intercultural learning experience, encourages social integration and increases future employability. Local communities are strengthened through European partnerships; the exchange of cultural knowledge and good practice also increases general awareness and understanding of international youth work. Immersion in a foreign culture is important to the personal development of young people, and their contributions to the charitable organisations also strengthen the European network.

Getting involved

To participate in EVS, organisations must first acquire accreditation. The first step to getting involved is to download and complete an Expression of Interest form (6 pages). These forms are accepted on a rolling basis; there is no deadline. Processing of accreditation can take up to six weeks and will involve a personal visit or a telephone interview. Once acquired, accreditation remains valid for three years.

For more information about the EVS, please contact [Julie Deléglise](#).

Annual Gala Concert

At this year's Gala Concert, the Belgian MS Society presented "Metropolis," Fritz Lang's silent film from 1927, with a live soundtrack performed by the National Orchestra of Belgium and conducted by Dirk Brossé. H.E. Prof. Dr. Reinhard Bettzuege, the Ambassador of Germany in Belgium, kindly accepted the role of Honorary President for the evening.

When was the first Gala Concert? The first one was in 1968, ten years after the National Belgian MS Society was founded. At that time, the concerts took place in a small concert hall. The audience grew each year, however, and in 1979 the decision was made to hold the concerts in the main Concert Hall in Brussels: Salle Henry Le Boeuf in the Palais des Beaux-Arts.

Who organises the event? The National Belgian MS Society, in cooperation with the two regional Belgian societies.

What is the purpose of the Gala? The Annual Gala Concert is a very important fundraising tool, and also provides valuable visibility for our Society to help raise public awareness for MS.

How long does it take to organise a gala of this scale? Initial preparation work, such as choosing the musical programme, generally starts about one year in advance. However, to have the orchestra and conductor of one's choice, planning should start as far as two or three years in advance.

The official planning of a specific event usually starts in September, six months ahead, with a mailing to our patron donors to announce the concert and begin fundraising. After that, we start to design the pamphlet and invitation card, send requests to sponsors and prepare the programme booklet for the evening.

We officially announce the concert two months beforehand with the mailing of about 5000 invitation cards. The ticketing opens six weeks ahead of the concert. This year about 1100 people attended. After the concert, we begin to follow-up the payments (such as tickets and sponsoring).

What are some difficulties you encounter when organising the event? The current organising committee has been in place for 14 years, so the preparation work goes very smoothly.

Will the event be held next year? We hope so, yes!

