

State of the Art of Rare Disease – Activities in EU Member States and Other European Countries

Hungary Report

Definition of a Rare Disease

Hungary has adopted the European Commission definition of a rare disease which the National Plan espouses. However there are instances where a different definition is used, the National Health Insurance Fund makes a distinction between rare and ultra-rare diseases.

National Plan/Strategy

Hungary has adopted a National Plan for rare diseases which planned to have a time frame of 2014 to 2020. Unfortunately the approval process for the National Plan has temporarily stopped due to the reorganisation of Hungarian Health authorities.

The National Plan for Rare Diseases has been reformulated and submitted as an application for Structural and Investment funds. The application is currently under review. There is dedicated funding for some of the activities of the National Plan but generally funding for activities of the national plan are incorporated into the general budget.

There is a dedicated body in place to oversee the drafting and implementation of the National Plan, it is partially functioning and does not include all relevant stakeholders. There is a Rare Disease Expert Committee works as an advisory group; the member experts were appointed by the Chief Medical Officer. Its members are from the four main medical universities: the Hungarian Medical Universities representatives to the national advisory group are nominated by the deans), governmental institutions, and patient organisations. This group has a key advisory function of strategic planning, but does not have influence and control on the implementation of the decisions made.

One of the major successes of the National Plan was the official approval of the Hungarian Centres of Expertise thus several health care providers were able to apply for membership in the forming of European Reference Networks.

Organisation of RD Health and Social Care

Centres of Expertise (CEs)

In Hungary there is an official policy for the designation of Centres of Expertise for rare disease, which has been fully implemented by 60/2003 decree of the Minister of Family Affairs, Health and Social Services regulate the CE designation.

There is a criteria which CEs need to fulfil in order to receive designation. The institution must provide diagnostic and/or therapeutic services for rare disease patients, and cooperate with other institutions to participate in rare disease care, contribute to the pathways organisation, provide multidisciplinary care, implement research and training projects and maintain registries for patients. The Minister responsible for health services designates the institution as a Rare Disease Centre of Expertise. Centres of Expertise ensure a holistic approach to care but they do experience difficulties.

European Reference Networks (ERNs)

Hungary has a formal process in place for the endorsement of Health Care Providers to participate as members or coordinators of a European Reference Network. At present there are 5 HCPs participating as full members of 10 ERNs in Hungary.

Members	European Reference Networks (ERNs)
Országos Onkológiai Intézet	ERN EURACAN
Semmelweis University	Endo-ERN ERN EURO-NMD ERN PaedCan

	ERN Skin ERN-RND VASCERN
Szent-Györgyi Albert Medical Center, University of Szeged	ERN Skin
University of Debrecen	MetabERN ERN Skin
University of Pécs	ERN CRANIO ERN EURO-NMD ERN GENTURIS ERN-RND

Rare Disease Registration

Neither national nor regional RD registries exist, but disease specific registries are available.

There is a legal framework in place to govern rare disease registration, provided by the general law and it concerns personal data protection in healthcare. For disease specific registries these are basically clinician-led. A national RD registry software is under development.

Genetic Testing

In Hungary disease specific registries are basically clinician led. Currently software for a national rare disease registry is under development.

Neonatal screening

In Hungary there is a compulsory screening programme for all new-born babies which is governed by Decree of the Minister of Health 44/2007. The following types of diseases are covered within the neonatal programme:

A total of 26 diseases are screened for within the neonatal programme. These include:

- 9 organic acidurias
- 7 amino acid metabolic disorders
- 7 fatty acid metabolism disorders
- 3 other metabolic disorders

Guidelines and training activities

Clinical Practice Guidelines (CPGs)

There are currently no Clinical Practice Guidelines produced in Hungary for rare diseases at the national level. There is a national policy for the development of CPGs but not for the adoption and implementation of Clinical Practice Guidelines.

Training and Education

Curricula of medical faculties contain courses dedicated to rare diseases, and there are courses which deal with rare diseases.

Information Resources for RDs

Orphanet Activities

Hungary has an operational National Orphanet team. It is coordinated by OTH within the National Public Health and Medical Officer Service and the Institute of Genomic Medicine and Rare Disorders within Semmelweis University who provide a project manager and information scientist.

The State Secretary of Health within the Ministry of Human Resources officially supports Orphanet.

The Orphanet team produces information in the Hungarian National language however there is no dedicated funding in place to support their activities. The Orphanet team have participated in many varied activities since the beginning of 2014:

- They have attended the European JA Orphanet meetings, and interpreted the conclusions of the previous period and the challenges of the present period for the Hungarian participants.
- Participated in conference calls with the project management of INSERM in order to discuss current issues related to Orphanet.
- Organised the kick-off meetings and presentations for the national expert centres for rare diseases in order to train the Hungarian experts and participants. The team launched written information for the leaders of all Hungarian centres of expertise for rare diseases about the data collection and operation of Orphanet.
- The team participates in Orphanet distance trainings organising by INSERM. The Team checks the latest updates of Orphanet regularly.
- The team uploads or facilitates for uploading the information of the Hungarian participants in all priorities (expert centres, laboratories and diagnostics, biobanks, mutations registries, patient registries, clinical trials, research projects and platforms) into the Orphanet database. The Team validates and updates of uploaded Hungarian data on the appropriate level.
- The team prepares guidance notes and manuals in Hungarian about Orphanet for Hungarian participants.
- The team initiates the nomination of representatives from every national Centres of Expertise for rare diseases in order to facilitate data collection.

National Helplines

There is a helpline in place within Hungary dedicated to rare diseases. It is funded through a mixture of public and private funding and is available for both patients and professionals. The helpline was established and is operated by the Hungarian Federation of People with Rare and Congenital Diseases (HUFERDIS - <http://www.rirosz.hu/>).

Official information centres

There are official information centres for rare diseases within Hungary. The NRDC is a part of and is maintained by the National Public Health and Medical Officer Service.

Rare Disease research activities

Existence of RD research programmes/projects

Hungary has specific programmes in place to fund and facilitate rare disease research in fact there is a specific programme of research for rare diseases which includes E-Rare-3 entitled "ERA-NET rare disease research implementing IRDiRC objectives" which is supported by the Hungarian Scientific Research Fund. A policy decision is currently under review which could allocate a proportion of the national research budget specifically to rare disease research. The total amount of public funds allocated to rare disease research each year is €150,000.

The socio-economic aspects of rare diseases are searched systematically in Hungary. There is no institution devoted at least partly to this purpose. HUFERDIS is participating in the InnovCare Project and has initiated a dialogue with the Ministry of Human Resources to research the socio-economic aspects further.

Participation in E-Rare and International Research Initiatives

Currently Hungary participates in E-rare.

National Alliance of Patient Organisations and Patient Representation

Hungary has a national alliance of rare disease patient organisations. The Hungarian Federation of People with Rare and Congenital Diseases (HUFERDIS) is the national alliance of 45 rare disease patient organisations in

Hungary, affiliated with EURORDIS. HUFERDIS was able to establish the "Lifebelt" Information Centre and Help Line for rare disease patients with the support of a Norwegian grant. Its work is essential to increase social awareness and the knowledge of health care professionals for the optimal implementation of the Rare Disease National Plan. Moreover, to improve patient awareness, and the development of peer communities. The necessary infrastructure was formed together with the help of a dedicated working group.

Through structured coordination the infrastructure was able to develop data bases, quality assurance, answering protocol, a non-disclosure agreement and an ethics code. Different communication channels were also developed which included a dedicated website, a Facebook page and a YouTube channel. All of which were introduced by several media campaigns and a final conference. HUFERDIS participates in several international projects including Europlan, Rare Disease Days, EUPATI and InnovCare which means it is well placed to ensure rare disease patients and healthcare professionals gain access to the most up to date information possible.

Integration of Rare Diseases to social policies and services

Specific actions exist to enable real access for people living with rare diseases to general social and disability programmes within Hungary. The current programmes are varied and offer rare disease patients a wide variety of assistance and support:

- Rarer Disease specific information centre is run by HUFERDIS.
- An official website of the National Office for Rehabilitation and Social Affairs provides information on all the social and child welfare services available in Hungary.
- The website, <http://info.kezenfogva.hu/>, provides information on benefits and allowances, sport and leisure programmes, social, child welfare, health care services and educational possibilities.
- A compulsory task of every municipality with a population of over 10,000 is to maintain a day care for people with disabilities. Every municipality must also offer care within rare disease patient homes. These services can be outsourced to NGOs or to churches.
- In case of the day care services eligibility is based on a medical document verifying the existing disability of the person, while in case of home care service a care needs assessment is necessary that determines the degree of care for supporting a self-sufficient life.
- Therapeutic recreation programmes are organized mainly by NGOs.
- The legal framework of employment for people with disabilities is the Act CXCI of 2011 on Benefits for Persons with Changed Working Capacity. The focus is on retained working skills, health condition, physical and mental capabilities in the care and occupational rehabilitation system of people with disabilities. In accredited employment there are two forms of benefits: 'transit employment' and 'long-term supported employment'. The accredited employer has to provide e.g. rehabilitation advisor, rehabilitation mentor and personal assistant if needed, and must have an occupational rehabilitation program and a rehabilitation plan.
- The other type of employment for people with disabilities is the social employment. It is under institutional care or use of social services getting intensive social assistance.
- The Rehabilitation Card is a tool for persons with disabilities to promote their employment in the open labour market.
- People with disabilities have the possibility to use home care service. To do so it is necessary to determine the degree of care required to live a self-sufficient life.
- Supported housing is more than just community-based services. It also provides housing and specific services that are based on the individual's needs but these services cannot be provided at the same place therefore urges people with disabilities to use community-based services and live a partly or fully self-sufficient life even if they do not live in their own homes.
- To facilitate a multidisciplinary, holistic and continuous care provision rare disease patients can have access to individual care plans which include access to social and support services.

Hungary is currently in the process of joining the InnovCare project which will provide further social integration support to rare disease patients.

Rare Disease Day

Hungarian organisations have planned many events to celebrate and promote rare disease day each year.

In 2014 and 2015 the following events took place:

In the central events, there were parallel professional programs in Budapest: Professional conference, useful programmes for families as well, like: patient organisations presentation booths, poster session, press conference, Play Space for the little once, with built up inside playground, handicraft, and entertainment like dance house, puppet show, and raffle. HUFERDIS took care about art as well with the Rare Beauties Collection exhibition and a RD photo competition. Similar programmes were organized by the University of Pécs; Debrecen; and Szeged as well.

Several other rare disease events were organised by the patient organisations:

- The World Days of different Rare Diseases.
- The final conference of "Lifebelt" Information Centre and Help Line project.
- The final conference of the "Leaving the Nest" project with the goal of the preparation of the young mentally challenged people (especially those affected with Williams syndrome and other rare diseases) for an autonomous life through work and trainings, that meet their needs and their personalities.

Other

No specific activity has been reported due to several elections and the reorganisation of government systems. However the main successes were:

- The Hungarian Centres of expertise were officially approved, thus several health care provider were able to apply for membership in the forming European Reference Networks.
- The RD specific information centre and help line was established by HUFERDIS

Information on Orphan Medicinal Products will be available in the next update.