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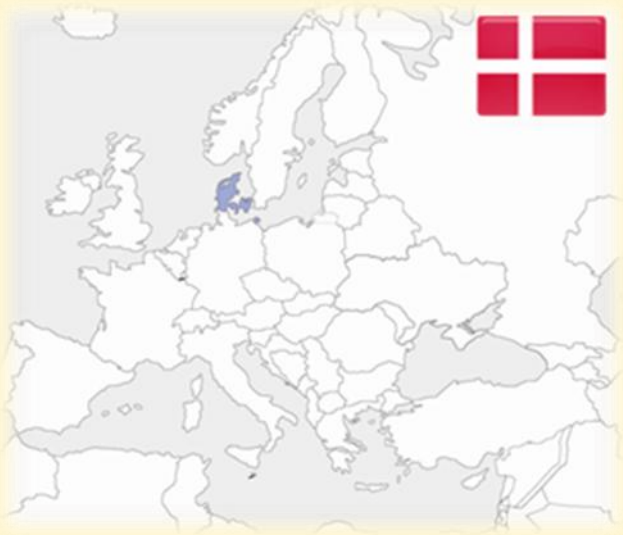
2012 REPORT ON THE STATE OF THE ART OF RARE DISEASE ACTIVITIES IN EUROPE OF THE EUROPEAN UNION COMMITTEE OF EXPERTS ON RARE DISEASES



STATE OF THE ART OF RARE DISEASE ACTIVITIES IN DENMARK

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More information on the European Union Committee of Experts on Rare Diseases can be found at www.eucerd.eu.

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ACRONYMS

General

CAT - Committee for Advanced Therapies at EMA
CHMP - Committee for Medicinal Products for Human Use at EMA
COMP - Committee on Orphan Medicinal Products at EMA
DG - Directorate General
DG Enterprise - European Commission Directorate General Enterprise and Industry
DG Research - European Commission Directorate General Research
DG Sanco - European Commission Directorate General Health and Consumers
EC - European Commission
ECRD - European Conference on Rare Diseases
EEA - European Economic Area (Iceland, Switzerland, Norway)
EMA - European Medicines Agency
ERN - European reference network
EU - European Union
EUCERD - European Union Committee of Experts on Rare Diseases
EUROCAT - European surveillance of congenital anomalies
EUROPLAN - European Project for Rare Diseases National Plans Development
EURORDIS - European Organisation for Rare Diseases
FDA - US Food and Drug Administration
HLG - High Level Group for Health Services and Medical Care
HTA - Health Technology Assessment
IRDiRC – International Rare Diseases Research Consortium
JA - Joint Action
MA - Market Authorisation
MoH - Ministry of Health
MS - Member State
NBS - New born screening
NCA - National Competent Authorities
NHS - National Health System
PDCO - Paediatric Committee at EMA
RDTF - EC Rare Disease Task Force
WG - Working Group
WHO - World Health Organization

Pilot European Reference Networks

Dyscerne - European network of centres of expertise for dysmorphology
ECORN-CF - European centres of reference network for cystic fibrosis
Paediatric Hodgkin Lymphoma Network - Europe-wide organisation of quality controlled treatment
NEUROPED - European network of reference for rare paediatric neurological diseases
EUROHISTIONET - A reference network for Langerhans cell histiocytosis and associated syndrome in EU)
TAG - Together Against Genodermatoses – improving healthcare and social support for patients and families affected by severe genodermatoses
PAAIR - Patients' Association and Alpha-1 International Registry Network
EPNET - European Porphyria Network - providing better healthcare for patients and their families
EN-RBD -European Network of Rare Bleeding Disorders
CARE-NMD -Dissemination and Implementation of the Standards of Care for Duchenne Muscular Dystrophy in Europe project
ENERCA - European network for rare and congenital anaemia – Stage 3

GENERAL INTRODUCTION TO THE REPORT ON THE STATE OF THE ART OF RARE DISEASE ACTIVITIES IN EUROPE OF THE EUROPEAN UNION COMMITTEE OF EXPERTS ON RARE DISEASES

The 2012 Report on the State of the Art of Rare Disease Activities in Europe was produced by the Scientific Secretariat of the European Union Committee of Experts on Rare Diseases (EUCERD), through the EUCERD Joint Action: Working for Rare Diseases (N° 2011 22 01), which covers a three year period (March 2012 – February 2015).

The report aims to provide an informative and descriptive overview of rare disease activities at European Union (EU) and Member State (MS) level in the field of rare diseases and orphan medicinal products up to the end of 2011. A range of stakeholders in each Member State/country have been consulted during the elaboration of the report, which has been validated as an accurate representation of activities at national level, to the best of their knowledge, by the Member State/country representatives of the European Union Committee of Experts on Rare Diseases. The reader, however, should bear in mind that the information provided is not exhaustive and is not an official position of either the European Commission, its Agencies or national health authorities.

The report is split into five parts:

Part I: Overview of rare disease activities in Europe
Part II: Key developments in the field of rare diseases in 2011
Part III: European Commission activities in the field of rare diseases
Part IV: European Medicines Agency activities and other European activities in the field of rare diseases
Part V: Activities in EU Member States and other European countries in the field of rare diseases

Each part contains a description of the methodology, sources and validation process of the entire report, and concludes with a selected bibliography and list of persons having contributed to the report.

The present document contains the information from Parts II and V of the report concerning Denmark. A list of contributors to the report and selected sources are in annex of this document. For more information about the elaboration and validation procedure for the report, please refer to the general introduction of the main report[1].

[1] http://www.eucerd.eu/upload/file/Reports/2012ReportStateofArtRDActivities.pdf

RARE DISEASE ACTIVITIES IN DENMARK

Definition of a rare disease

There is no official absolute definition for rare diseases at the moment in Denmark. The National Board of Health tends to define rare diseases as affecting no more than 500 patients in the Danish population. Rare Disorders Denmark (The national alliance of patient organisations for rare disorders) defines rare diseases as affecting no more than 1'000 patients in the Danish population. The Danish definition also takes into account the degree of complexity of the disease, and the general rules that the disease must be severe, genetic or congenital, therefore rare cancers and infectious diseases are usually not considered to be part of the concept of "rare diseases" in Denmark.

National plan/strategy for rare diseases and related actions

Access to health care at hospitals and GPs is free of charge for all citizens independently of diagnoses and prevalence. Patients also have a right to choose between relevant hospitals. Access to social services and support for patients is also free of charge and given depending on need.

There is currently no national/strategy plan for rare diseases in Denmark involving all sectors, but regarding the hospital sector the Danish National Board of Health as the statutory competent authority has approved centres of expertise/referral centres for rare diseases in 2010 as part of a comprehensive planning of highly specialized hospital services in Denmark accordingly to the health care act.

Since 1993 The National Board of Health has published a catalogue of centres of expertise designated by the National Board of Health. This catalogue of centres has been revised regularly through the years and is now developed to the above mentioned approval system.

In 2001 the Danish National Board of Health launched a special report on rare diseases with recommendations regarding rare diseases in general and specific recommendations for 14 rare diseases to be cared for at two specialised Rare Diseases Centres. These two centres were established in Copenhagen and Aarhus respectively. In the beginning the centres where mainly focused on paediatric patients. Now about one third of the patients are adults. The two centres work continuously on strengthening the interdisciplinary and cross professional activities. The 2001 report also gave a number of other recommendations which have not yet all been implemented. The report describes an ideal general model for development of activities regarding rare diseases in the health care sector and cooperation with other sectors. Many of the EUROPLAN-recommended elements of a national strategy for rare diseases are dealt with in this report.

Current expenditure for rare diseases, as for all other diseases, is within in the general health system budget of the regions and municipalities. There are no dedicated funds for rare diseases, except for the dietary treatment of phenylketonuria which is directly financed from the state budget. In 2010 special funding was obtained from the state budget to implement a National Center for Rett syndrome within the Kennedy Center.

On 19 November 2010, Rare Disorders Denmark in collaboration with EURORDIS held a National Conference on Rare Diseases[2] in the context of the Europlan project in order to discuss the elaboration of a national plan for rare diseases in Denmark. During 2011 it was decided to let the National Board of Health establish a working group to elaborate a national strategy for Rare Diseases.

The working group has a broad representation of stakeholders, to elaborate a national plan for RD, was founded at the end of 2011 and met at the start of February 2012 for the first time. The recommendations in previous report on rare diseases from 2001 will be assessed to see what is still needed, what has changed and what new recommendations can be added considering the European perspective and the recommendations for a national strategy.

Centres of expertise

The National Board of Health has the authority to approve centres of expertise accordingly to the Health Care Act.

As mentioned above two centres of expertise specific for rare diseases have been functioning officially since 2001 in the health care system in Denmark at university hospital level. There is also a number of other

[2] http://download.EURORDIS.org/europlan/2_EUROPLAN_Guidance_Documents_for_the_National_Conference/final_report_denmark_europlan.pdf

established referral centres/centres of expertise approved by the National Board of Health to maintain a specific or several specific rare diseases[3].

The two centres, Clinic for Rare Disabilities – KSH in Copenhagen and Centre for Rare Diseases – CSS in Aarhus, were established in 2001, being responsible centres for 14 specific diagnoses. The special remit of these centres is the co-ordination of patient-care programs, treatment protocols and databases, and taking care of medical highly specialised tasks in agreed partnerships. Two years after the establishment of the centres, Rare Diseases Denmark conducted a survey that revealed that 75% of patients felt they had received better and more coherent treatment when treated at the centres. The two centres also have an important function in assessing patients, who do not have a diagnosis, but where a rare disease is suspected. Today the centres take care of many more different diagnoses, which do not have another nominated centre.

According to the Danish Health Care Act from 2007 the National Board of Health began a comprehensive work going through the organization of specialized diagnoses, treatments and medical technologies across 36 surgical, medical and diagnostic specialties. The main goal was to improve quality through sufficient volumes of patients and experienced professionals. The general criteria for establishing centers of expertise in this context are rareness, complexity, multidisciplinarity and costly technologies. In 2009 public and private hospitals could apply to the National Board of Health for approval to maintain specific specialized treatments. In 2010 the National Board of Health announced the approved hospital departments.

The two Centres of Rare Diseases have also been approved in this context. The departments that host the two Centres of Rare Diseases have also been approved for a number of different rare diseases, e.g. in Copenhagen for inborn errors of metabolism (IEM).

The number of centres of expertise for a single condition or groups of conditions depends on rarity (estimated number of patients), competence and available technology. A specific condition might thus be treated at only one specialised hospital department or up to five different hospital departments. Some geographical considerations will usually play a role in the decision making process if there is room for more than one centre. The approved departments are required to secure and develop their expertise, establish a quality improvement programme, document their activities and take part in teaching and research activities. The system is focused on treatment of patients.

The National Board of Health has in this new National Plan for highly specialized hospital services issued about 1100 approvals of medical highly specialized functions and estimates that about 100 of these are related to various diseases or groups of diseases which can be classified as rare. In General the approvals will last for a duration of 3 years thereafter a revision is due.

Pilot European Reference Networks

Danish teams participate, or have participated, in the following European Reference Networks for rare diseases: Dyscerne, EPI, NEUROPED, Paediatric Hodgkin Lymphoma Network, PAAIR, EN-RBD and Care-NMD

Registries

No single centralised register for rare diseases currently exists in Denmark, but a number of different registries and biobanks exist although there is currently no public register giving an overview of the existing registries and biobanks dealing with rare diseases. The Serum Institute has hosted registry and biobank of all newborn screening blood samples since 1980. The Kennedy Centre maintains biobanks on specific rare disorders as Menkes disease and various genetic eye diseases. All visually handicapped children are registered until the age of 18. Furthermore, several research departments have registries of rare diseases patients. The Raredis database which collects clinical data has been developed in Denmark in accordance to the recommendations in the Danish report of rare diseases from 2001 and has been in function since 2007 at the two Centres of Rare Diseases in Denmark. Up to 2010 there is collected data on 1800 patients with 561 different diagnoses seen at the two centres. Centres of rare diseases in the Nordic countries use their local version of Raredis for collecting clinical data. The hereby collected information can be used for research projects and bench marking at a Nordic level for different rare diseases. Specific research projects are planned.

The Danish National Patient Registry (NPR) exists since 1977 and collects systematic information on diagnoses, surgical treatment, and various demographical parameters on all patients admitted to hospital or similar institutions in Denmark.

Denmark contributes to some European registries such as EUROCARE CF, EIMD, EMHG and EUROCAT.

[3] For more information: *Centres of Reference for RD in Europe: State of the art in 2006 and recommendations of the RDTF* (p.9) http://www.eucerd.eu/upload/file/Publication/RDTFECR2006.pdf

Neonatal screening policy

National neonatal screening schemes are in place for phenylketonuria, congenital hypothyroidism, congenital adrenal hyperplasia, maple syrup urine disease, ASL, carnitine transporter defect, medium chain acyl-CoA dehydrogenase deficiency, long-chain 3-hydroxyacyl-CoA dehydrogenase deficiency, very long chain acyl-coA dehydrogenase deficiency, glutaric acidemia type 1, methyl malonic acidaemia, propionic acidaemia, multiple carboxylase defect**,** arginino succinic aciduria**,** tyrosinemia type 1 and biotinidase defect. Furthermore, the timing for drawing the blood samples (done by heel-prick) has been brought forward from five days to within 48-72 hours following birth, allowing for earlier intervention and treatment. Neonatal hearing screening has also been introduced as part of the national policy.

Genetic testing

There are 6 approved highly specialised centres for clinical genetic testing and counselling. Some genetic testing is also carried out in a few clinical biochemistry laboratories (e.g. BRCA testing). Genetic testing abroad is possible mediated by the clinical genetics centres. Genetic testing for medical reasons is part of the national health care system and free of charge. State reimbursement of costs for tests abroad can be effected after approval from the National Board of Health.

Diagnostic tests are registered as available in Denmark for 139 genes and an estimated 205 diseases in the Orphanet database[4].

National alliances of patient organisations and patient representation

Rare Disorders Denmark (RDD), founded in 1985, is the national alliance of 43 rare disease patient organisations/societies. In addition there are further 20 other patient organisations for rare disorders. Patient organisations are eligible to receive limited funding from the Ministries of Health and Social Affairs and have an obligation to capacity build in order improve integration of patients in schools and at the work place. RDD has a small professional body of staff, in cooperation with the Danish Haemophilia Society. RDD facilitates exchange of experience between the member societies and advocate the rights of all rare disease patients.

Rare Disorders Denmark has developed a tool, Social Profiles, to promote dialogue between rare disease patients and professionals. The profiles are currently available for 23 rare diagnoses, with more to come. The profiles are published on the "Rare Citizen" website[5].

Rare Disorders Denmark RDD holds a mini-roundtable with relevant pharmaceutical companies. The mini-roundtable has 8-10 members.

In 2011, RDD had the following main activities:

1. Lobbying for a national plan for rare diseases and handicaps. In May 2011, RDD published and disseminated a booklet about the importance of a national plan and throughout the year met with politicians and civil servants to promote the forming of a working group.
2. Developing a special training programme for rare disease families with children under the age of 18 – "Rare Family Days". In the framework of a randomised study, two family courses were conducted for 16 families. The results will be published in 2012, along with a new concept for "Rare Family Days".
3. Cooperating with the Centre of Disability and Social Psychiatry (ViHS) to transfer a Focus Point of Contact for very rare disease patients and relatives with no possibility to join or form a patient organisation/society. RDD built and ran a temporary website for dialogue between the members of the Focus Point and prepared to fully take over the Focus Point in 2012.
4. In June 2011, RDD participated in the EURORDIS POLKA project as a work package leader: among other activities, RDD performed a survey in cooperation with the Centre of Expertise in Aarhus, University Hospital of Skejby. The aim of the survey was to discover the perception of the quality and more of the Centre from health care professionals and rare disease patients.

Patients' organisations are, in general, consulted regarding legalisation concerning issues relevant to rare diseases and, in general, participate in the relevant boards and official bodies/working groups. Rare Disorders Denmark is represented on an advisory board of the Centre for Disability and Social Psychiatry (ViHS) and in the working group of National Plan, constituted by the National Board of Health in December 2011.

[4] Information extracted from the Orphanet database (September 2011).

[5] www.sjaeldenborger.dk

Sources of information on rare diseases and national help lines

Orphanet activities in Denmark

From 2004-2010 there was a dedicated Orphanet team in Denmark, hosted by the John F. Kennedy Institute. This team was in charge of collecting data on rare disease related services (specialised clinics, medical laboratories, ongoing research, registries, clinical trials and patient organisations) in the country for entry into the Orphanet database.

Official information centre for rare diseases

The state-funded information centre on rare diseases, the Danish Centre for Rare Diseases and Disabilities (*Center for små handicapgrupper*[6]) has been functioning since 1990 with a public database containing short descriptions in Danish on rare diseases. The centre provided information, as well as guidance, especially on social issues, and provided contact with patient organisations. The CSH also ran a rare disease help line which provided information and support. The CSH maintained a database of approximately 400 rare disease patients who are currently without patient organisation representation for their disease. The CSH also contributed to Rarelink.eu, the Nordic website compiling links relating to information on rare diseases.

At the end of 2010, the Ministry for Social Affairs closed the Centre for Rare Diseases and Disabilities (*Center for Små Handicapgrupper* – CSH) as an independent institution. This decision was a consequence of the merger of 3 information and knowledge networks and 13 research centres in areas overseen by the Ministry of Social Affairs to form a new Centre for Disability and Social Psychiatry (*Videnscenter for Handicap og Socialpsykiatri* - ViHS[7]) as of 1 January 2011. In October 2010, the Minister for Social Affairs met with the Centre for Rare Diseases and Disabilities (*Center for Små Handicapgrupper* – CSH) and Rare Disorders Denmark concerning this merger. The plans have been met with concern regarding the continuation of the services provided by CSH. The experience of the first year of the new structure is that the help line is functioning well, but that the knowledge-based work with short diagnosis descriptions has become more difficult and is not at the same level as before. The future general information about rare diseases is expected to be discussed in the working group of the National Strategy.

Help line

Up until 2010 CSH ran a rare disease help line which provided information and support. As a result of the reorganisation of the CSH, there is established a dedicated "Rare Disability Team" within the ViHS's counselling service which mans the help line from January 2011 onwards.

Other sources of information

No specific activity reported.

Good practice guidelines

The 2001 report from the National Board of Health laid down guidelines concerning 11 specific rare diseases. These guidelines also serve as template concerning other rare diseases. Health care professionals consult published international guidelines.

Training and education initiatives

The two Rare Diseases Centres participate in educational activities for nurses and doctors. Furthermore, they provide teaching of other health care professionals, families, teachers and caretakers.

National rare disease events in 2011

To mark Rare Disease Day 2011, Rare Disorders Denmark encouraged policy makers and others stakeholders to become friends of the Day. In addition, the alliance launched a new feature on its website, "Rare stories". This section gives patients, caregivers and others interested in rare diseases the opportunity to tell their own story and share it with others[8]. In addition, in November 2011, a nordic conference about Huntingtons Disease was held in Copenhagen.

[6] www.csh.dk

[7] More information on the organisation of the ViHS can be accessed here http://www.csh.dk/fileadmin/pdf/Rapporter_og_andet/Organisering_af_ViHS-1.doc (accessed 27/01/2011)

[8] www.sjaeldnediagnoser.dk/historier

Hosted rare disease events in 2011

In 2010 the following rare disease events were announced in *OrphaNews Europe*: VI Cornelia de Lange Syndrome World Conference (27-31 July 2011, Copenhagen), European Conference on Post Polio Syndrome (31 August – 02 September 2011, Copenhagen).

Research activities and E-Rare partnership

National research activities

There are no specific programmes for rare diseases research in Denmark or focussed calls/grants. Although there are no specific initiatives to support research into rare diseases in Denmark, Danish researchers are active in the field and there are resources in place (biobanks, registries, databases) for rare disease research.

Participation in European research projects

Danish teams participate, or have participated, in a number of European research projects for rare diseases, including: ALPHA-MAN, CILMALVAC, EURHAVAC, EIMD, EMSA-SG, EUROCRAN, EUROGLYCANET, EUROPEAN LEUKEMIA NET, EMVDA, EUNEFRON, HDLOMICS, HUE-MAN, HUMALMAB, LEISHMED, MMR-RELATED CANCER, MYASTAID, NEUROKCNQPATHIES, NEUROPRION, NM4TB, PULMOTENSION, SPASTICMODELS, SIOPEN-R-NET, SERO-TB, TB TREATMENT MARKER and VACCINES4TB.

E-Rare

Denmark is not currently an E-Rare partner.

IRDiRC

Danish funding agencies are not currently committed members of the IRDiRC.

Orphan medicinal products

Orphan medicinal product committee

There is currently no committee dedicated to Orphan medicinal products and/or rare diseases in Denmark.

Orphan medicinal product incentives

Upon request, the Danish Medicines Agency may provide free scientific advice in the development of orphan medicinal products[9].

Orphan medicinal product market availability situation

Out of 68 orphan medicinal products with an EU market authorisation, 58 are approved in Denmark and are on the Danish national formulary of medicines[10] . The approval process usually takes 6-8 weeks.

The list of orphan medicinal products approved and launched on the market in Denmark includes: Afinitor, Aldurazyme, Arzerra, Atriance, Busilvex, Carbaglu, Cayston, Ceplene, Cystadane, Diacomit, Elaprase, Esbriet, Evoltra, Exjade, Fabrazyme, Firazyr, Firdapse, Gliolan, Glivec, Increlex, Inovelon, Kuvan, Litak, Lysodren, Mepact, Mozobil, Myozyme, Naglazyme, Nexavar, Nplate, Orfadin, Pedea, Prialt, Replagal, Revatio, Revlimid, Revolade, Savene, Soliris, Somavert, Sprycel, Tasigna, Tepadina, Teysuno (S-1), Thalidomide Celgene, TOBI Podhaler, Torisel, Tracleer, Ventavis, Vidaza, Volibris, Votubia, VPRIV, Vyndaqel, Wilzin, Xagrid, Yondelis, Zavesca.

Orphan medicinal product pricing policy

Manufacturers and importers of pharmaceutical products are free to set the price of each pharmaceutical. However, orphan medicinal products are mostly hospital-only pharmaceuticals, and the drugs used at hospitals are bought via public procurement. Most public tenders are carried out by AMGROS which is a hospital purchasing agency owned by the five regions in Denmark.

Orphan medicinal product reimbursement policy

There is no reimbursement policy that pertains specifically to orphan medicinal products. In many cases, orphan medicinal products are restricted to hospitals. All medicines dispensed at hospitals are free of charge to the patient, and if dispensed from a pharmacy on prescription there is a needs-based co-payment[11].

[9] This section is written with information from the *Inventory of Community and Member States' incentive measures to aid the research, marketing, development and availability of orphan medicinal products. Revision 2005* (pp10-11)

[10] www.medicinpriser.dk

Other initiatives to improve access to orphan medicinal products
According to the *Inventory of Community and Member States' incentive measures to aid the research, marketing, development and availability of orphan medicinal products*, there are no specific programmes to facilitate the provision of medicines to rare diseases patients in Denmark (i.e. compassionate use). However, in special circumstances and to a limited degree the Danish Medicines Agency can authorise "*the sale or dispensing of medicinal products that are not marketed in Denmark for other purposes than clinical investigations (cohort or named patient supply). Patients with life-threatening diseases for which there are no well-documented treatment options can be offered experimental treatment (named patient supply only)*" [12].

Orphan devices
No specific activity reported.

Specialised social services
Respite care services are sometimes provided by municipalities. Patient organisations organise informal therapeutic recreational activities and can sometimes receive government financial support. Services are provided and funded by the government to enable help integrate patients with rare diseases into daily life, both at school and work.

DEVELOPMENT OF RARE DISEASE ACTIVITIES IN 2011 IN DENMARK

National plan/strategy for rare diseases and related actions
During 2011 it was decided to let the National Board of Health establish a working group to elaborate a national strategy for Rare Diseases. The working group has a broad representation of stakeholders, to elaborate a national plan for RD, was founded at the end of 2011 and met at the start of February 2012 for the first time. The recommendations in previous report on rare diseases from 2001 will be assessed to see what is still needed, what has changed and what new recommendations can be added considering the European perspective and the recommendations for a national strategy.

National alliances of patient organisations and patient representation
In 2011, Rare Disorders Denmark had the following main activities:

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[11] *EMINET Initial investigation to assess the feasibility of a coordinated system to access orphan medicines*, C. Habl & Florian Bachner, p.47.
[12] This section is written with information from the *Inventory of Community and Member States' incentive measures to aid the research, marketing, development and availability of orphan medicinal products. Revision 2005* (p10)

University Hospital of Skejby. The aim of the survey was to discover the perception of the quality and more of the Centre from health care professionals and rare disease patients.

Sources of information on rare diseases and national help lines

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National rare disease events in 2011

To mark Rare Disease Day 2011, Rare Disorders Denmark encouraged policy makers and others stakeholders to become friends of the Day. In addition, the alliance launched a new feature on its website, "Rare stories". This section gives patients, caregivers and others interested in rare diseases the opportunity to tell their own story and share it with others[14].

Hosted rare disease events in 2011

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Research activities and E-Rare partnership

IRDiRC

Danish funding agencies are not currently committed members of the IRDiRC.

[13] More information on the organisation of the ViHS can be accessed here http://www.csh.dk/fileadmin/pdf/Rapporter_og_andet/Organisering_af_ViHS-1.doc (accessed 27/01/2011)

[14] www.sjaeldnediagnoser.dk/historier

LIST OF CONTRIBUTIONS[15]

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  www.rarelink.dk
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  http://www.orpha.net/national/DK-DA/index/homepage/

[15] The contributors and validators of the report have contributed information which is accurate to the best of their knowledge. However, readers should take note that the contents of this report are illustrative and not exhaustive.
[16] All websites and documents were last accessed in May 2012. A more detailed list of sources is available in the full report: http://www.eucerd.eu/upload/file/Reports/2012ReportStateofArtRDActivities.pdf