

Annex 9: **Tour de Table**

Participants to the discussion in plenary were representatives from Ministries of Health from 16 EU MS: Austria, Belgium, Croatia, Estonia, Germany, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Romania, Slovakia, Slovenia, Spain, Sweden. Hungary and the UK were represented by delegates of patient organisations.

Disclaimer: following are the opinions of the individual officials and not of the organisations they represented.

Malta

Malta has no National Plan for RD approved yet. The draft of the Plan for RD needs to be “reviewed” before being adopted.

Several good registries have been established for areas such as cancer, congenital anomalies, treatments received abroad, orphan drugs.

In terms of coding, ICD 10 is being presently used and the introduction of Orphacode is desirable but seems to be problematic. At present, it is not clear how to link the two systems but there is an interest in eventually do it. It was proposed that a meeting of those involved in RD coding in Malta would be a good step forward.

Netherlands

As for Malta, coding seems to be the main problem in the Netherlands as well. Harmonisation is required in the field of RD coding. There are also needs around cross-border healthcare, and how this should operate in practice.

Romania

Romania has adopted the National Plan for RDs and the main problem now is its implementation. At present, the methodological processes needed to implement the plan it are still missing. Romania uses ICD 10 for its coding, and, at the time being, it appears that it may be difficult to introduce a new coding system.

UK

For what concerns the UK, the main challenge is that there are four different nations, which should work together on RD but, in practice, this does not happen often. In fact, it is difficult to bring these Countries and their different systems together. The Welsh have launched a public consultation on the implementation of their Plan, and the Scottish team is drafting its views.

Belgium

Belgium has already approved the National Plan for RDs and it plans to implement the Orphacode. The interpretation of the Orphacode was discussed.

Sweden

The representative from Sweden, being fairly new to the role and to RDs, was unsure about the coding system used in the Country and will raise these issues with colleagues once back to Sweden. Sweden has a national function working with RDs. One of its tasks is to stimulate the development of regional centers for RDs in Sweden.

Ireland

The Country is considering linking national expertise with expertise abroad. The representative first raised the question of how to participate in the forthcoming ERNs. The second key question concerned how to structure and coordinate relationships with CEs in a small country and island-nation such as Ireland. In such a case, the value in exchanging information and data sharing is

therefore even greater. However, data sharing involves both technical and legal issues and these will need to be identified and resolved.

Russia

(The representatives were delegates of patient organisations)

In Russia there is a nosological registry for statistical/epidemiological purposes, but without a medical component. This includes 213 diseases but does not include all the RDs.

According to the delegates, education is their main problem (in the sense of needing to educate the population of Russia about the problems of RDs). They felt their participation in the workshop to be very important in order to gain some knowledge useful for organizational perspective and experience.

Australia

Australia is still evaluating the need for a National Plan for RDs. They have learned a lot from European approaches and have used and European experience to model their own health system. Using EUROPLAN experience and tools, they have elaborated 59 recommendations, in collaboration with patient organizations, informing the healthcare system about RD issues.

Austria

The representative found that the questionnaire was confusing but feels it is acceptable to use it as a pilot. Given the fact that the wording was confusing and there was no indication of the aims of the exercise or what the results were to be used for, the Austrian representative cautioned against placing undue emphasis on the 'results' of the exercise.

Austria has developed a draft of the National Plan (which in a sense is somewhere between a strategy and a plan). All major stakeholders were included in the process, especially RD patient organisations.

A number of challenges have been identified. For instance, budget is a challenge, as several institutions are involved.

Furthermore, the Austrian representative stated that it would be useful to have European guidelines on the following subjects: Grouping of diseases, Registries, and Coding.

Among the opportunities, the EUCERD Recommendations were considered useful tools. In particular, the 'EUCERD Recommendations on Quality Criteria for CEs' were considered very useful and Austria has adapted them to the Country needs, considering the Austrian context.

Austria has initiated cooperation in RDs with Germany, given the geographical proximity and the fact that these countries have quite similar healthcare systems. However, it was stated that there is a need for a wider cooperation, both at the European as well as at local level.

Estonia

Estonia also found the questionnaire confusing. The representative did not understand what each answer meant and what was supposed to be used for. Nevertheless, the representative of Estonia declared of having responded to the questionnaire as best she could, according to her personal point of view.

Estonia has adopted a National Plan for RDs, which is currently undergoing translation into English.

Estonia does not plan to set up a national registry for RDs as there is a national health information system in place with data on patients. There is a single centre of expertise for RD in the Country, that is a University Hospital.

Lithuania:

Lithuania has adopted a National Plan for RDs in 2012 and, at present, an English version of the Plan is not yet available. Despite the Plan, the lack of budgetary resources is slowing down the implementation process.

Lithuania seeks support in the field of registries, guidelines, and grouping of diseases by CEs.

The Lithuanian society for Human Genetics has organised, in collaboration with Eurordis, the national EUROPLAN conference. The conference was organised under the auspices of the Lithuanian EU Presidency.

Georgia

Georgia does not have a NP for RDs. There is a working group (involving EUROPLAN) which is helping them to draft the Plan.

The MoH has adopted guidelines for some diseases. Likewise, working groups on different themes e.g. accreditation and training, social services and CEs have been created and assistance is needed regarding the recognition of CEs.

Bulgaria

Vladimir Tomov – President of the Bulgarian National Alliance for RDs – organised a EUROPLAN National conference in 2010.

The first National Plan for RDs was adopted in 2009 for a period of four years and it has ended in December 2013.

The issue of registries still remains high on the agenda, as previously. Working Groups at the MoH are currently working on a 2nd plan for RDs 2014-2018, and the main problems at present relate to registries, social services and to a regulation for guidelines.

At the end of 2013 new rules for RDs have emerged, in the form of an Act, in order to fill the gap on registries for RDs and on the current regulations.

Slovakia

As a small country, Slovakia reported that it was useful for them to listen to other countries' experiences.

The National Strategy has been adopted and Slovakia is now working on a National Plan. However, though the NP has not yet been officially adopted, the MoH is working already on the implementation phase. This way, when the NP will be adopted, the implementation phase can start right away.

The MoH is supporting doctors and patients in using existing international registries in fields such as Cystic Fibrosis and neuromuscular disorders. Slovakia is involved in EUROCAT, and is conducting a pilot project on virtual registry of rare diseases, to find workable solutions on how to collect the data about rare disease patients in the country, using ICD 10 codes OMIM, and Orphacode.

Slovenia

Slovenia adopted a National Plan in 2012, complete with specific actions but, since then, little has been done in terms of implementing it. The MoH has recently appointed a Working Group to implement the NP starting with information to patients.

In Ljubljana, a centre for undiagnosed rare diseases has been established at the Clinical institute of medical genetics (CIMG), University Medical Centre Ljubljana (following the example of the NIH programme for undiagnosed patients). They also have a Centre for Mendelian Genomics. They have new equipment for genetic testing which saves them money, allowing them to send fewer

samples for testing abroad. CIMG offers genetic testing for most of the currently known monogenetic genetic disorders. CIMG is as well member of EUROCAT. Slovenia is also envisaging establishing a national registry for RD and is interested in the experience of other European countries. A new Healthcare Databases Act is in preparation.

There is an interest to receive - via a seminar or a webinar - more information on the implementation and evaluation of the French National Plan.

Hungary

After the approval of the National Plan for RDs, elections took place in Hungary. Currently there is a feeling that there may be a lack of support for the National Plan but, in the future, there is hope that the focus may be brought back to RDs and to the implementation of the Plan.

Italy

As yet, Italy has no approved National Plan for RDs, although one should soon be adopted. Italy is also interested in sharing the experiences of other countries.

The Italian representative has pointed out that the Country has a good legislation and a national registry for RDs that is effectively working. Italy has to improve the internal RD network, in terms of exchanging information and experiences more effectively, and devise a better way of organising their structures.

Orphacode is considered a good opportunity if a way is found to integrate Orphacode with the present coding system.

Germany

The German representative did not fill in the questionnaire as she did not feel entitled to answer solo and without notice and information.

The German National Plan was adopted earlier this year by NAMSE – A German league of different stakeholders including the German MoH and ACHSE, the German National Alliance of Patients' Organisations. The NAMSE has not yet disclosed the budget; however, each stakeholder has committed to finance the project/activity in which it is involved. The German MoH has a budget of 5 million euros. The plan has involved 28 stakeholders and 52 action proposals were elaborated.

Regarding a registry, the question remains, according to the German representative: "what is a registry"? A national RD registry does not exist in Germany and there is no plan to establish one, as extracting data would be too complicated from a legal point of view. Instead, it will be necessary to adopt 'phonebook' architecture (a registry of registries) and an interface to localize the existing data.

Germany has adopted ICD-10 with its own coding modifications = ICD-10 GM. Currently, Germany is trying to establish links between ICD10 GM and Orphacode. To this end, the MoH has initiated a project to manage the interchange of information between Orphacode and ICD10. A second project being funded by the MoH deals with data sharing, to allow the different registries to communicate with each other (OSSE). Dr Weber will give a talk on this subject, soon.