Jim Higgins (MEP from Ireland, Vice-Chair of the Interest Group)
“Welcome and Introduction”

Mr Higgins started the session by welcoming all participants to the 12th meeting of the Interest Group (IG) on Rheumatic and Musculoskeletal Diseases (RMDs). He emphasised the burden of RMDs on the economy and society of the EU and the need to further implement actions to better prevent and treat these conditions. In this context, the new EU Data protection legislation is important as it will have an impact on the work of the scientific community. In particular, it will establish new rules for the use of patients’ personal data in the medical research.

Takis Hadjigeorgiou (MEP from Cyprus, Vice-Chair of the Interest Group)
“Overview of the theme of the meeting”

Mr Hadjigeorgiou briefly introduced the topic: The New EU Data Protection Regulation (DPR). By doing so, he summarized its genesis. The new DPR was intended to strengthen individual rights and thereby tackle some of the challenges of globalization and new technologies. Moreover, the new regulation is following a twofold task, ensuring the free flow of personal data while protecting it at the same time. Furthermore, Mr Hadjigeorgiou outlined the key positions and issues in the current debate around the Commissions’ proposal for the new Regulation. It was also mentioned that the Parliament will vote on the amended report in the responsible committee (LIBE committee) on 21 October.

Thomas Zerdick (Head of sector Data protection reform, DG Justice, European Commission):
“The European Commission’s proposal: Data protection & research”

Mr Zerdick began his speech by explaining the importance of and the need for a new Data Protection Regulation. According to him, it is vital to develop a European digital economy, to react on the changing digital environment and build trust among citizens, businesses and other stakeholders. The current legislative framework on data protection is effective since 1995. However, this legislation left a fragmented data protection law among Member States and led to obstacles for the free flow of data. With regard to the impact of the new legislation on scientific activities, he stressed that it is
important to find a right balance between DPR and the use of data as well as storage of it - especially with regard to storage allowance for medical research as laid down in Art. 83 of the Commission’s Proposal. In order to achieve this balance, he suggested establishing best practice as follows: Use anonymised data as default; if personal data is used, it should be pseudonymised and only in last instance use identifiable data.

**Dr Bonnie Wolff-Boenisch (Head of Research Affairs, Science Europe):**

*“The scientific health community perspective”*

Dr Wolff-Boenisch emphasised the importance to modulate the level of protection according to the type of data and research field.

She then highlighted the main concerns of the research community with regard to some aspects of the proposed regulation. With regard to the provision of explicit consent, some research could become illegal under the new rules, since it appears to be complicated to obtain approval from a relatively vast number of patients within a certain time frame when working with large databases. Further, in some cases the need for identifiable data does exist, especially when it comes to personalised medicine and genetics. Dr Wolff-Boenisch concluded that reusing and mining of data amounts to a major part of medical research activities, thus the legal implications have to be considered, in particular the clarification of using pseudonymised data. Last but not least, she stressed the need for an appropriate legal framework for medical research, as these activities will become even more important to address the increasing incidence of chronic diseases in the future, partly due to the ageing of the population in Europe.

**Antoine Fobe** (EU and International Affairs Unit, Commission nationale de l'informatique et des libertés, CNIL)

*“CNIL perspective on Data protection”*

Mr Fobe started his presentation by mentioning the importance of consent for data collection and processing. This concept of consent had already been established under current data protection law. This measure, he added, should be mandatory even in case of data processing in the public interest. Among others, Mr Fobe also suggested that key-coded (pseudonymised) data should not be subject to exception from the Regulation, since the majority of processed data, especially for commercial use, is already key-coded. Therefore special rules and safeguards are required for this type of data as well.
Nick Meade (Patients Network for Medical Research and Health - EGAN)

"The patients’ perspective"

Mr Meade started his presentation by drawing on a hypothetical case of a child with several rare conditions. Based on this, he highlighted the strong link between health research and medical care. Following this line of argument he explained that data processing is not conducted in isolation, but rather in research networks. Under the premise that the EU has a mandate to facilitate medical research in Europe he pointed out that it is difficult to rely only on the use of anonymised data, especially in the field of rare diseases research and personalised medicine.

He concluded with a perspective focussing on the entire population. According to it, further genetic research is strongly needed to improve the knowledge in a comparatively young field of science. In order to reach that goal it would be necessary to avoid unnecessary restrictions to access to data.

Mr Jim Higgins (MEP from Ireland, Vice Chair of the Interest Group)

“Discussion with participants”

Participants started a vivid discussion touching the different aspects of the new DPR. Mr Fobe stressed the need for a narrowed down concept of “broad consent”, which also holds true for data processed in medical research. This was contested by Dr Wolff-Boenish who emphasised the need to simplify the process of obtaining the broad consent. According to her, the processing of data for the purpose of medical research should be subject to specific rules.

Susan Oliver from EULAR added that in general, patients are willing to provide their records for the purpose of further research. Mr Zerdick commented that the Commissions’ proposal outlines the work that still has to be done by the Member States in order to harmonise laws on data protection. The proposal is setting general meaningful guidelines and building up on the framework which has been already recognised by the scientific community. Further, harmonised framework on data protection is also required in regards to the handling of electronic health records and the implementation of the EU Directive on Patients’ Rights in Cross-Border Healthcare, according to Karolina Hanslik, a policy officer at DG SANCO. In addition, the participants elaborated on the definition and use of pseudonymised (key –coded) data. Since there is a possibility to decode this data, it was agreed that key-coded data are to be classified as identifiable data and hence they should be subject to the Regulation.

At the end of the debate Mr Higgins thanked everyone for the participation in the meeting and for the fruitful contributions. Mr Hadjiheorgiou concluded with thanking the participants for the valuable input and expressed his confidence that both sides will reach the “golden line” between individual data privacy and a high quality in health research.
About rheumatic and musculoskeletal diseases
Chronic rheumatic and musculoskeletal diseases affect almost one-quarter of all Europeans (more than 120 million). These people have impaired quality of life, various degrees of disability and often premature death. Rheumatic diseases elicit the highest costs to health care and social systems. In Europe alone, due to health care costs, work-disability, sick leave and premature retirement, rheumatic diseases impose an economic burden of more than € 240 billion per year on state budgets. The impact of these diseases is expected to grow immensely due to demographic and lifestyle changes.

About EULAR
The European League against Rheumatism (EULAR) is the European umbrella organisation in the area of rheumatic and musculoskeletal diseases. EULAR represents scientific societies, health professionals associations and organisations of people with arthritis/rheumatism throughout Europe. The aims of EULAR are to reduce the burden of rheumatic diseases on the individual and society and to improve the treatment, prevention and rehabilitation of musculoskeletal diseases. More information on www.eular.org.

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