UPDATE ON THE NATIONAL ACTIVITIES RELATED TO THE EU REGULATIONS - ICELAND

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THE PRESENT SYSTEM 1

- Icelandic Medicines Agency (IMA) evaluates the quality of the investigation and investigational medicinal product and the overall safety of participants in clinical trials.
- The legal framework for the IMA is national law on medicinal products (93/1994) with corresponding amendments and national Regulation 443/2004 which implements the 2001/ 20 EU Regulation.
- National Bioethics Committee (NBC) reviews the ethical part and issues that have to do with the participants and data related to them.
- Since 2008, the NBC is the only EC in Iceland to assess applications for conducting clinical trials in the country.
- The NBC's legal framework 44/2014 implements international practice, recommendations and conventions and national law, including i.a. the Helsinki Declaration and European Conventions etc.
- Before a clinical trial can be started approval must be obtained from IMA and the NBC

THE PRESENT SYSTEM 2

- Part of the NBC's assessment of an application is to get an evaluation by the Data Protection Authority (DPA) on how sensitive information, including bio-samples and medical records, are accessed and handled in the study, and how such data is secured, kept or destroyed. The DPA has 10 working days to evaluate these issues. The application forms to NBC for approval of clinical and other health related studies was worked out jointly by the NBC and the DPA and contains sufficient information for the DPA's assessment.
- The average handling time by the NBC, including the 10 days detour to the DPA, is about 28 working days
- The assessment of applications can take place simultaneously by the IMA and NBC

THE NEW REGIME

- It is mandatory that the legislation and procedures in Iceland in this field are in harmony with international practice and law
- Iceland is looking towards Denmark and other Nordic countries when it comes to the implementation of the EC Regulation 536/2014, on clinical trials, taking the difference in scale into account

THE NEW REGIME 2

- The IMA reviews the medical and pharmaceutical parts (Report 1) and will be the reporting instance on behalf of Iceland. The NBC will cover the ethical aspects in Report 1 and 2, including how to approach eventual participants, the communication with the DPA, access to medical records and bio-samples, informed consent etc.
- The IMA will house the access point to the national IT system for clinical trials. Discussions between IMA and EMA are underway.
- A secure information gateway will be established between the IMA and the NBC.
- There is already a similar gateway between the NBC and the DPA for the exchange of applications and other sensitive documents and confidential information.

THE NEW REGIME 3

- There is no general need to restructure the legal framework for the NBC, but it will be ensured that one of the members, appointed without nomination, will be selected from lay people from the entry into force of the EU Regulation.
- Presently the NBC's services are free of charge but this will probably change and amendment to the law is necessary for that end.
- Presently the NBC convenes every two weeks and this meeting frequency may have to streamlined according to process and timelines of trials to be assessed.
- Definitions of responsibilities in the assessment of future clinical trials, reporting and practical cooperation between the IMA and the NBC are under way. This includes workflow processes, access to documentation, timing etc.