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EU Register of Clinical Trials Launched Online

All EU citizens can now access information on the thousands of authorised pharmaceutical clinical trials that are underway in the EU. The aim of this official public register is to make clinical research on pharmaceuticals more transparent for patients and others and to avoid unnecessary duplication of clinical trials. Every year approximately 4000 clinical trials are authorised in the EU. Since most of them last 2 to 3 years, this means that around 10,000 trials are ongoing at any given time.

John Dalli, European Commissioner for Health and Consumer Policy, said : "The register launched today is good news for patients as it will allow them to get easier information about clinical trials going on in the EU, possibly giving access to important new treatment. It is also of great interest to healthcare professionals and carers, the research community and industry."

More Transparency

The Clinical Trials register contains information about clinical trials authorised in the EU, whether they take place in one Member State or several. It includes clinical trials conducted by both industry and research institutions. The information is rendered public once the clinical trial has been authorised.

The register also includes the clinical trials contained in a Paediatric Investigation Plan - the research and development programme that aims to generate the data required to authorise a medicinal product for use in children. The clinical trials contained in such a Plan are published even if they are performed outside the EU.

Management of the Register

The European Medicines Agency is responsible for the day-to-day management of the online register. The sponsor of the clinical trial (the responsible party for the trial) provides and updates the information in the register via the national competent authority of the country, or countries, in which it is being conducted. The register is part of the overarching EU public database EudraPharm, which also centralises information on medicines authorised by the EU, such as the patient information leaflet.

Background

Clinical trials are investigations in humans intended to discover or verify the effects of one or more investigational medicinal products. The aim of a clinical trial is not necessarily to apply for a future marketing authorisation. Clinical trials can also be conducted for studies on authorised medicines – for example, a comparison between two authorised medicines.

Clinical trials performed in the EU must be conducted in accordance with the EU Clinical Trials Directive (2001/20/EC) and its implementing legislation which lays down principles and detailed guidelines for good clinical practice for investigating medicinal products for human use. This legislation aims at ensuring a high level of protection of patient safety, as well as reliability and robustness of the data generated in a trial. To this end, the legislation and implementing guidance specify various aspects of clinical trials including:

- Information that must be submitted to the competent authorities and to the ethics committees;
- Requirements for 'informed consent' of the clinical trial participants;
- Requirements on safety monitoring and the reporting of adverse reactions;
- Requirements regarding Good Clinical Practice, including the documentation, of the clinical trials;
- Specific requirements regarding the products tested, including manufacturing and labeling; and
- The inspections of competent authorities and applicable procedures.

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