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Impact of the Clinical Trials Directive: 3000 Clinical Researchers Protest

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Some 3,000 researchers have signed a petition against Directive 2001/20/EC on Clinical Trials 2001, which took effect in May 2004. The campaign against the directive will now focus on documenting the difficulties experienced by researchers as a result of the transposition of the directive into national law. In Ireland, for example, the number of applications submitted to carry out clinical trials has fallen by half since the measure was adopted. Furthermore, the European Institute of Oncology in Milan has seen the cost of its clinical trial insurance policy increase from 13,000 in 2003 to 108,000 in 2004.

In a further development, Australian biotech company, Sirtex Medical Limited, has indicated that increased costs directly attributable to the directive were behind its decision to move the latest phase of its clinical trials out of Europe. Many of the large pharmaceutical companies have unofficially halted all new investigator led research while they determine the precise implications of the directive for the research process. The group behind the petition published these and other findings on its website, www.saveeuropeanresearch.org. It has forwarded this information to the European Commission requesting a response.

Workers Health and Safety Given a Boost

The Council of the European Union on 6/7 December 2004 reached political agreement on a draft European Parliament and Council Directive on minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents, concerning optical radiation.

The draft Directive lays down minimum health and safety requirements regarding exposure to such risks, with the objective of achieving harmonisation of control regimes between Member States. It also places a range of duties on employers, including the requirements to assess risk, reduce exposure, undertake health surveillance and provide information and training to workers.

The Directive's provisions rely upon guidelines for restrictions on exposure that have been produced by the International Commission for Non-Ionising Radiation Protection (ICNIRP). The draft text follows separate Directives on minimum health and safety requirements regarding the exposure of workers to risks arising from mechanical vibration, noise and electromagnetic fields.

After its finalisation in all Community languages, the text as agreed will be adopted in the form of a common position, without further debate, at a forthcoming Council's meeting, and to be sent to the European Parliament with a view to its second reading.

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