European Society of Radiology

Alliance for MRI

Statement by Prof. Gourtsoyiannis, President of the European Society of Radiology

The European Society of Radiology is today launching the 'Alliance for MRI', together with Dr Swoboda, member of the European Parliament and Vice-Chair of the Party of European Socialists, and Ingele Meulenbergs of the leading European patient group, the European Federation of Neurological Associations (EFNA).

The 'Alliance for MRI' is a coalition of European Parliamentarians, patient groups, leading European scientists and the medical community, who together are seeking to avert the serious threat posed by EU health and safety legislation to the clinical and research use of Magnetic Resonance Imaging (MRI).

MRI equipment is an essential tool in diagnosing and treating illness and in medical research. MRI scans produce detailed pictures of the inner structure and function of patients' bodies using strong magnetic fields and radio waves. It is central to important treatments and research programmes for many illnesses, in particular cancer, heart disease and neurological problems.

In 2004 The European Union adopted the EU Physical Agents 2004/40/EC (EMF) Directive to reduce adverse health effects on workers linked to short-term exposure to electro-magnetic fields. The deadline for implementing the Directive is April 2008.

However, the European Commission's original impact assessment (which was ten years old) did not cover the social and economic consequences of legislating in this area. As a result, the impact on the use of MRI, while unintended, has serious consequences for healthcare provision and patient welfare.

1. It threatens clinical and research use of MRI.

2. It will make it more difficult for healthcare staff to care for patients, such as children, the elderly or those who are anaesthetized, who need help or comfort during scans. Some of these patients may be forced to use technologies with significant proven health risks, such as X-Rays.

3. It will stop the use of MRI for interventional and surgical procedures.

4. It will curtail cutting edge research in the field of MRI, denying patients innovative treatments in the future.

The Directive establishes exposure limits for workers (MRI practitioners and those maintaining the equipment) from zero to 300Ghz. These limits are based on hypothetical and incomplete information. At a recent ICNIRP[1] workshop, statements by the Chairman of ICNIRP and the European Commission acknowledged the uncertainty of the scientific basis of the Directive. According to the Chairman of

[1] 14-16 February 2007 Workshop of International Commission on Non-Ionizing Radiation Protection: The European Commission used the ICNIRP 1998 Guidelines as the basis for Directive 2004/40/EC.

ICNIRP, the limits in the intermediate frequency range (500-1000 Hz) ‘can be questioned’ and the European Commission acknowledged that the suggestion that there were 'solid effects' at 500-1000 Hz was 'perhaps not right'.

Any decision to severely curtail the use of MRI must be based on firm scientific evidence. MRI has been safely used for over 25 years, with over 500 million patients exposed to up to 100 times the occupational exposure limit set by the Directive, without evidence of harm to workers or patients. It is essential that this major advance in healthcare technology is not threatened by burdensome legislation, when concerns can be addressed through responsible guidance to medical and service personnel.

The Alliance for MRI requests that, as a matter of urgency, the European Commission:

1. Inform Member States, notably Ministries of Health, as well as implementing ministries and agencies, of the unintended consequences of the Directive;

2. Inform Member States of the Commission’s expert study currently being undertaken into the impact of the Directive on MRI, and request a delay in implementing the legislation until the results of the study are known (expected in October 2007);

3. Propose an amendment to the legislation, introducing an EU-wide derogation for MRI.

Statement by Professor Gabriel P. Krestin

President Barroso is the champion of an innovative and competitive Europe. I urge him and his colleagues to take a closer look at how Directive 2004/40/EC (EMF) threatens the use of Magnetic Resonance Imaging (MRI) and will make Europe less healthy and less competitive.

MRI is not only one of the most important scientific advances in the field of medicine in the last 25 years, but also one of the major tools in medical and biological research. The technology was mainly developed in Europe and the threat posed by the EU Directive is recognized by Nobel laureate Sir Peter Mansfield, who in 2003 was awarded the prestigious prize for his seminal discoveries in the field of MRI.

The Directive will make the examination of many patients with life-threatening illnesses such as cancer, brain tumours, stroke or heart attack, practically impossible. Our estimates show that this could affect up to 8 million MRI examinations performed in European Union Member States per year. Among those, more than 400,000 procedures on patients such as children or the very sick, who need to be accompanied near the scanner, would be precluded, as would close monitoring of MR examinations under anaesthesia, which is required by approximately 80,000 patients. In addition 10,000 cases of cutting edge interventional MRI procedures would be prohibited.

Implementation of the Directive into national legislation by April 2008 will threaten the EU’s position as leader in MRI research – an area where we are at the cutting edge of scientific developments, contributing to an innovative and competitive Europe.

Hospitals, health authorities and research institutes in Europe will no longer invest in MRI technology if they are potentially exposed to the threat of being sued. I already see this in my own hospital in Rotterdam, where decisions have to be taken for future imaging equipment in operating rooms. The European Commission cannot attempt to remedy the situation through explanatory technical guidelines to member states on how to implement the legislation. We need legal certainty.

To achieve this, the European Commission must inform member state governments of the unforeseen consequences of the Directive. If member states implement the legislation as it stands, MRI practitioners and patients will be forced to go to those countries which, (against EU law) introduce a national derogation for MRI when transposing the Directive. (Austria and Finland are already proposing such derogation).

I very much hope that the President of the European Commission will look into this issue and provide leadership to his services to rectify the unintended consequences of this piece of legislation. To implement it in its present form would pose a serious threat to public health and biomedical research in Europe.

Professor Gabriel P. Krestin is Professor of Radiology at Erasmus MC, University Medical Center Rotterdam, in the Netherlands. He is also chair of the Research Committee of the European Society of Radiology, Past President of the European Society of Magnetic Resonance in Medicine and Biology and Founder of the European Institute for Biomedical Imaging Research.