



PRESS RELEASE

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Alliance for MRI welcomes postponement and amendment of the EU Directive on electromagnetic fields to protect MRI

The Alliance for MRI welcomes the European Commission's announcement today that it will postpone and amend legislation which would pose a serious threat to the use of Magnetic Resonance Imaging (MRI) in patient welfare and scientific research.

The EU Physical Agents Directive 2004/40/EC (EMF) is to be delayed by four years until 30th April 2012 to allow time for a substantive amendment to be adopted. The Alliance welcomes the Commission's statement that "the future amendment will aim to ensure that limits will not have an adverse effect on the practice of MRI" and the recommendation to Member States to put the transposition of the current Directive on hold.

The use of MRI has provided immeasurable benefits to patients. It 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 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.

If implemented, the Directive would prevent healthcare staff from assisting or caring for patients during imaging. It would mean that some patients who cannot be imaged without this care – if they are young, elderly, frail or confused – would either be denied imaging or have to undergo alternative procedures such as X-rays.

"MRI is a powerful, non-invasive and safe diagnostic and research tool," says Professor Gabriel Krestin, a leading member of the Alliance for MRI and Professor of Radiology at Erasmus MC, University Medical Center Rotterdam, in the Netherlands. "However, its application often relies crucially on the presence of a healthcare worker or researcher. If the European Commission legislation were implemented, it would almost certainly impact on patient welfare and be a major setback for scientific research, denying patients innovative treatments in the future."

The Alliance for MRI, which represents a coalition of European Parliamentarians, patient groups, leading European scientists and the medical community, has campaigned to bring attention to the potential plight of patients.

In June 2007, the Alliance for MRI held a lunch at the European Parliament with Commissioner Spidla to discuss research undertaken by Professor Stuart Crozier of Brisbane University, Australia¹, which vindicated the Alliance's concerns.

In addition to its serious impact on healthcare, the Alliance believes the Directive would threaten Europe's position as world leader in MRI research, as recognized in the Nobel Prize awarded to Sir Peter Mansfield. MRI is a leading example of where the EU is in the forefront of cutting edge research, and thereby contributing to an innovative and competitive Europe.

"We look forward to working with the European Commission prior to the proposal to amend the directive," says Professor Krestin. "It is essential that the European Commission assesses closely the full impact the directive will have, taking into consideration the social, economic and environmental impact of the legislation.

"Any new legislation must be evidence-based and founded on sound science. There has been no proven harmful effect of MRI to either patients or workers over the past 25 years, during which time over 500 million examinations have been undertaken."

The Alliance for MRI believes that it is essential to evaluate the real risk to patients which would be brought about by impeding the full use of MRI, against the notional and unproven risk to workers.

The Alliance for MRI believes that a derogation for MRI from the scope of the EU Physical Agents Directive 2004/40/EC (EMF) is necessary to ensure the future unimpeded use of MRI, particularly for cutting edge research and interventional MRI. 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 safety of MRI workers is already regulated by the EU Medical Devices Directive (amend. Direct 93/42/EEC) and the established MR safety standard IEC/EN 60601-2-33 (as amended to include users/workers). The IEC standard establishes limit values for time-varying electromagnetic fields which have been set so that any danger to patients and workers is excluded.

Quotes

'MRI is a powerful tool that is of vital importance in the diagnosis and treatment of many diseases. I am delighted that the European Commission has decided to delay implementation of the EMF directive. This decision will allow essential investigations and procedures to continue to be carried out and is undoubtedly in the best interests of patients.' **Professor Andreas Adam, President of the European Society of Radiology**

¹ Study Commissioned by the UK Health and Safety Executive
<http://www.hse.gov.uk/research/rrpdf/rr570.pdf>

'I very much welcome the European Commission's willingness to amend the EU Physical Agents Directive on Electromagnetic Fields so that we can continue the clinical and research use of MRI. The safety of all MRI workers – I count myself among them - is taken very seriously and radiologists would not be willing to expose ourselves or our employees to harmful effects in the workplace. In 20 years of working with MRI, I never experienced any effect and definitely no harmful effect being exposed to the EMF fields exercised during MR examinations. Best practice guidelines including extended information and instruction of workers at MRI installations is the most appropriate and sensible way forward. I hope that decision-makers will recognize the need to exempt MRI from the Directive so that patients can continue to benefit from the progress we have made in the diagnosis and treatment life-threatening diseases.' **Professor Gabriel P. Krestin, Professor of Radiology at Erasmus MC, University Medical Center Rotterdam.**

'EFNA welcomes the European Commission's decision to postpone the 'EMF Directive'. This is in the best interest of patients who are reliant on the latest developments in MRI. It will be essential that any amended version of the Directive allow the important research and surgical procedures to continue in this area.' **Mary Baker, President, European Federation of Neurological Associations (EFNA)**

"We are delighted that the European Commission has recognised our concerns about the prohibitive impact the Directive would have on cutting-edge MRI research, diagnosis and treatment. MRI provides crucial insights into human physiology, health and disease. However, we know from research led by the Wellcome Trust, more than half of MRI research depends on the researcher being able to stand close to the scanner to work with patients and equipment, and this work would have been prevented by the Directive." **Dr Mark Walport, Director of the Wellcome Trust**

"The European Society for Therapeutic Radiology and Oncology (ESTRO) welcomes the postponement of the Physical Agents EMF Directive. The successful treatment of the various diseases relies heavily on accurate and reliable diagnosis. The increase in cancer survival seen over the past decades is, to a large extent, due to more precise diagnostic tools - MRI included. Impeding the medical use of MRI would have severe impact on treatment out-come of cancer patients in Europe. The European Commission must learn from their experience with this Directive and consult widely before implementing Directives that impact negatively on research and patient care." **Professor Dag Rune Olsen, Chairman of ESTRO Physics Committee**

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Background on Alliance for MRI

The Alliance is supported by:

26 Members of the European Parliament

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European and National patient groups European Federation of Neurological Associations (Founding member); including the European Parkinson's Disease Association, The European MS Platform and the European Headache Alliance, The European Heart Network, Europa Donna, The European Patients Forum, The International Diabetes Federation – Europe, Alzheimer Europe, The WHO Collaborative Centre for Research, training and treatment in Epilepsy, The Austrian Lung Association, The Austrian Epilepsy Association, Werkgroep Hersentumoren vzw (Belgian Brain Tumour Group), Epilepsy Centres of the Netherlands Foundation: SEIN

Representative Groups of Scientists

- European Society of Radiology (Founding Member) and institutional members (below)
- The Wellcome Trust
- European Society for Magnetic Resonance in Medicine and Biology (ESMRMB)
- European Union of Medical Specialists
- European Brain Council
- Luxembourg Medical Council
- European Institute for Biomedical Imaging Research (EIBIR)
- The Society and College of Radiographers
- European Society for Therapeutic Radiology and Oncology (ESTRO)
- European CanCer Organisation (ECCO)

Institutional members of ESR:

- Société Française de Radiologie (SFR)
- Spanish Radiological Society (SERAM)
- Polish Medical Society of Radiology
- Norwegian Society of Radiology
- Royal Belgian Radiological Society
- Luxembourg Society of Radiology
- Deutsche Roentgenesellschaft - German Radiological Society (DRG)
- Radiological Society of the Netherlands
- European Society of Urogenital Radiology (ESUR)

- European Society of Thoracic Imaging (ESTI)
- European Society of Neuroradiology (ESNR)
- Croatian Medical Association & Croatian Society of Radiology
- European Society of Cardiac Radiology (ESCR)
- Italian Society of Radiology (SIRM)
- European Society of Breast Imaging (EUSOBI)
- Romanian Society of Radiology
- Danish Society of Radiology
- Austrian Radiologic Society (ÖRG)
- British Institute of Radiology
- Swedish Society of Medical Radiology
- Bulgarian Association of Radiology
- Sociedade Portuguesa de Radiologia e Medicina Nuclear
- Czech Radiological Society
- Faculty of Radiologists, Royal College of Surgeons in Ireland
- European Society of Head and Neck Radiology
- Cardiovascular and Interventional Radiological Society of Europe
- The Royal College of Radiologists

In addition, a number of individual scientists and patient group representatives have signed up to the Alliance

Further information is available at <http://allianceformri.org>

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