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The Alliance for MRI - The Commission Responds

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The 'Alliance for MRI', a coalition of European Parliamentarians, patient groups, leading European scientists and the medical community was launched during the ECR 2007, to avert the threat posed by EU health and safety legislation to the clinical and research uses of MRI.

Background of the Directive

In 2004, the EU adopted the EU Physical Agents 2004/40/EC (EMF) Directive to reduce adverse health effects on workers linked to short-term exposure to electromagnetic fields. The deadline for implementing the Directive is April 2008.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, such as:

•It will curtail clinical and research implications of MRI;

•It will make it more difficult for healthcare staff to care for high-risk patients, who may be thereby obligated to use alternate technologies with proven risks, (e.g., x-ray or CT);

•It will arrest the use of MRI for interventional and surgical procedures; and,

•It will inhibit research in the field of MRI, denying patients innovative treatments in the future.

Goal of the Alliance for MRI

The Alliance for MRI requests that 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 Commssion'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.

Recent Update: The Commission Responds

In response to the concerns raised by the Alliance for MRI, the following letter was sent jointly from Directors General Mr. Van der Pas (DG Employment) and Mr. Madelin (DG Health and Consumer Affairs).

"The European Commission is aware of the concerns expressed by the European Society of Radiology regarding the possible impact of Directive 2004/40/EC on the medical use of Magnetic Resonance Imagery.We are taking those concerns seriously. The Commission has already taken a number of initiatives, in full transparency and cooperation with interested parties, including the ESR. Firstly, the European Commission will shortly be writing to national authorities alerting them to the issue and asking them about any difficulties they may have faced during the process of transposing Directive 2004/40/EC.

Secondly, we have brought the issue to the attention of Member States and the social partners in the framework of the EU Advisory Committee for Safety and Health at Work.The Advisory Committee has mandated a working group to assist the Commission in finding a resolution to issues regarding unintended effects of the Directive on the use of Magnetic Resonance Imaging. This will include analysing research emerging from

various member states and the Commission, formulating potential solutions, and providing a draft opinion for adoption by the Advisory Committee.

Thirdly, we are following closely, relevant studies undertaken on this issue, and in particular the forthcoming report from the study launched in the UK by the Health and Safety Executive (HSE).The HSE will be invited to share the results of this study, which should become available in April 2007, with the Commission and the Advisory Committee.

Fourthly, the Commission has published a tender for an independent study in order to assess the implications for MRI of the exposure limit values imposed by the Directive and to identify problems, if any, in a quantitative and comprehensive way. This study will be undertaken in close cooperation with the users and manufacturers of MRI equipment. We are pleased that the Alliance has agreed to be associated with this study. The first results should be available by October of this year and will be submitted to the Advisory Committee as soon as possible. Finally, the Commission is in regular contact with the International Commission on Non-Ionising Radiation Protection and other relevant international bodies to collect information on the latest technical and scientific evolutions. If, at any of the above stages, substantial evidence becomes available that the exposure limits laid down in the Directive would unduly affect medical procedures, we will be prepared to address the problem, not excluding a proposal to amend the Directive."

Growing Support for the Alliance for MRI

The Alliance is supported by twenty leading MEPs, eight European and national patient groups and four representative groups of scientists. In addition, a number of individual scientists and patient group representatives have signed up to the Alliance NEXT STEPS European Parliament Lunch to be held Wednesday 13th June to inform members of the European Parliament of the scientific basis for the concerns regarding the impact of the EMF Directive. Information regarding the Alliance for MRI will be posted on the ESR website www.myESR.org and further information is available from Ms. Monika

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