Statement of the European Society of Human Reproduction and Embryology (ESHRE) on the European Commission proposal of viral screening in assisted reproduction treatments

16 November 2009

With 900,000 assisted reproduction treatments annually such as IVF and intrauterine inseminations in Europe the Commission's proposal to screen both partners before each treatment could lead to costs of over EUR 140 million annually. These figures do not include the additional overhead costs such as administration, personnel and documentation that the hospitals would have to carry on top of that. The new interpretation of the EU Directive would have substantial implications on the costs of fertility treatments in Europe.

On 19-20 October in a meeting with the National Competent Authorities, the Commission stated that in terms of the directive, all patients must be tested for HIV, hepatitis, Human T-lymphotropic virus, and syphilis prior to each treatment and that this is not open for national interpretation.

Assisted Reproductive Technology (ART) is currently covered under the European Union Tissues and Cells Directive (EUTCD; EC/2004/23), a legal document originating from the European Union's public health programme. The Directive covers donation of all tissues and cells within the EU (except blood and blood-products).

Sperm samples from couples who are married or have been together for several years are treated as 'partner donation'. However, couples seeking assisted reproduction generally undergo a series of treatments in one year instead of one single donation as is the case for organ or tissue donations. So testing would have to be done for the same couple and for each treatment.

Currently 500,000 IVF treatments are performed in Europe, on top of these come 400,000 intrauterine inseminations (IUI). Since both partners need to be screened this would lead to 1.4 million tests a year. With an average cost of EUR 100 per test kit, this would result in a cost burden of EUR 140 million for the European ART sector.

"In the history of ART and the area covered by the Directive there has been no single documented report of viral transmission", explained Dr. Søren Ziebe from the University Hospital of Copenhagen. "How can we document something that never happened?" he added. This interpretation will have a profound impact on all units conducting assisted reproduction.

Most national authorities are in line with ESHRE and see this interpretation of the Directive as not relevant to the ART sector. "The ART field should have a separate specific Directive given that ART is so

different in its specifications compared to tissue or organ donations", said Prof. Jean Francois Guérin, from the University of Lyon.

ESHRE acknowledges that non-partner donation is an area with separate requirements. In Denmark viral screening for diseases such as HIV or Hepatitis B is valid for 24 months. In France it is valid for up to 12 months. At the moment the period of validity is interpreted by the national authorities and there seems to be different interpretations and practices at the national level. "It has been suggested to establish a formal working group with professionals in the field of ART and other relevant professionals such as microbiologists as well as national regulators", explained Dr. Søren Ziebe. "This group, if established by the Commission, could be very useful in order to reach a consensus in this area", he said.

Attachments: ESHRE position paper on the EU Tissues and Cells Directive EC/2004/23, November 2007