EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate B - Health systems, medical products and innovation
B4 – Medical products: quality, safety and innovation

Meeting between European Society for Human Reproduction and Embryology (ESHRE) and DG SANTE B4

16th September 2016

Summary Minutes

Background and Agenda:

The main aim of the European Society of Human Reproduction and Embryology (ESHRE) is to promote interest in, and understanding of, reproductive biology and medicine. It does this through facilitating research and subsequent dissemination of research findings in human reproduction and embryology to the general public, scientists, clinicians and patient associations; it also works to collaborate with politicians and policy makers throughout Europe. Membership of the Society is open to all individuals active in the field of reproductive medicine and science including medical doctors, scientists, students and support personnel. It promotes improvements in clinical practice through organizing teaching and training activities, developing and maintaining data registries and providing guidance to improve safety and quality assurance in clinical and laboratory procedures. With 6,000 members, it is the largest society of its kind globally and it organises a scientific meeting attended by around 10,000 participants each year.

ESHRE had asked to meet European Commission representatives to discuss how activities related to data collection and publication in the field could be better co-ordinated and improved and what the future of the EU legislation covering assisted reproduction technologies might be.

The chair of ESHRE had organised the meeting in 2 parts, the first part was attended by the ESHRE chair, past chairs, chair-elect, the chair and chair-elect of the European IVF Monitoring (EIM) steering committee, the chair of the European Affairs Committee, the communications manager and the managing director of the ESHRE office. The second part was attended by the same participants along with all of the other members of the Executive

Board of ESHRE. Part I focused on current and future data collection and analysis and the second part on the EU legislation.

The European IVF Monitoring (EIM) Consortium

ESHRE presented the work and results of the EIM consortium. The consortium is a group of representatives of national ART registries that gather data on a voluntary basis to build the European register that is held by ESHRE. In 2013, the data was provided by 35 countries covering the activity of 1,144 centres, 684,065 cycles and the birth of 143,597 children. It is estimated that the registry contains around 80% of the total ART activity in Europe. The data is provided by the national authority in many countries and directly by the clinics in others. In around half the countries, data reporting is mandatory and complete, and in the other half it is voluntary and not provided by all centres. Ten countries collect the data by individual cycle while the others report cumulative data. Eight countries provide public access to data at the clinic level.

The registry shows steadily increasing activity over the 16 years since it was launched. It also provides data on the techniques applied and the developing relevance of those techniques over the years including the transfer of fresh embryos after IVF, the freezing of embryos and oocytes, the use of intra-cytoplasmic sperm injection (ICSI), IUI, egg and embryo donation etc., relating them to outcome in terms of pregnancy or, more recently, live birth. It demonstrates increasing success over time, the increasing use of IVF with ICSI (as opposed to IVF alone) and a strong trend towards the safer practice of transferring fewer (or only 1) embryos. It also includes information on complications that occur, although this does not extend to the monitoring of child born from ART and therefore the transmission of genetic abnormalities is not recorded in the registry.

ESHRE noted that many countries also report the legally required annual report of serious adverse reactions and events (SARE) for the European Commission to the Eurocet registry (www.eurocet.org), however much data is lacking in this registry. The SARE data is reported by numbers of gamete units distributed while the EIM data is reported by cycle. It was agreed that the Commission should explore the possibility of changing to numbers of cycles to facilitate the data gathering. In general, ESHRE felt that efforts should be made to rationalise these data gathering efforts.

The future of the collection of ART data in the EU

ESHRE presented a critical evaluation of the current registry conducted by the EIM consortium, considering its strengths and weaknesses and the opportunities that might exist for improving it. The key weaknesses relate to the lack of any legal basis for the reporting of data on a multinational basis and the need for robust financial support for improving and sustaining the registry. The current registry does not measure or track cross-border activity (donation or treatment) and it is often based on cumulative, rather than single cycle data.

ESHRE would urge that data reporting, by cycle, should be mandatory at the EU level. They would propose that a single upgraded registry should be developed through collaboration between ESHRE, the EC and the Member State Competent Authorities, to allow electronic data submission, analysis and publication. Donors and patients should be identified via a unique code that would allow the follow up of donors and children born, for the detection of unexpected adverse outcomes. The effort should be state/EU funded and the data should be published in an anonymous manner that would allow it to be used as a learning tool. It was noted that in some countries electronic systems are already in place that could be seen as models for an EU-wide system.

EU Legislation for assisted reproduction

DG-Sante presented an overview of the EU legislation in the field of substances of human origin, with an emphasis on the ART field. They outlined recent changes to the legislation, relating to coding and import requirements. Information was provided regarding the Commission's SARE data collection and reporting and the Rapid Alert platform that regularly communicates cases of genetic transmissions by sperm. The Public Health Programme has funded a number of projects and joint actions that aim to support the implementation of the legislation. It was noted that ESHRE has participated in some of those actions. A new Joint Action, VISTART, will look at the important areas of vigilance, inspection and coding, supporting Member States in improving and harmonising their activities in these regulatory fields. VISTART is seen as an important opportunity to agree improvements to activities such as data reporting and analysis at an EU level.

ESHRE was informed that an in-depth formal Evaluation of the EU blood and tissue & cells legislation is likely to start later in 2016. It will include a series of proscribed steps including consultation on an evaluation roadmap and timetable, a contracted service for part of the evaluation and ample opportunities for targeted and public consultation where stakeholders will be able to share their views. ESHRE will be an important stakeholder in that process.

Meeting close

Both parties expressed their satisfaction with the very useful exchange of information and their agreement to maintain an open dialogue and collaboration on the topics discussed.