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 DG SANTE (Unit B4), the Federation of Danish Enterprise and Cryos International

26 October 2017

Draft Summary Minutes

Participants:

The Federation of Danish Enterprise (Chamber of Commerce, Transparency Register number: 0330934426-12)

Cryos International (Transparency Register number 963595828688-36)

DG SANTE represented by Unit B4 - Medical products: quality, safety, innovation

The Federation of Danish Enterprise had requested a meeting with DG SANTE (SANTE B4) on behalf of its member, Cryos International. The request followed from the participation of Cryos International in a Public Stakeholder Event held in Brussels on September 20th 2017 as part of an ongoing evaluation of the EU legislation on blood, tissues and cells. The aim was of this meeting was to provide more detailed information to DG Santé on some of the issues raised during the stakeholder event. Both the Federation and Cryos had submitted to the Open Public Consultation held during the summer of 2017.

1. The Federation of Danish Enterprise thanked DG Santé for agreeing to meet and explained that they are a non-profit private organisation representing companies in Denmark, including Cryos International, many private hospitals and psychiatric homes and some assisted reproduction clinics.

2. After the introduction of the participants, Cryos International introduced its new Regulatory Compliance Manager and outlined the key issue it wished to raise during the meeting: patient access to medical treatment with donor gametes and the impact of legislation on this. DG Santé stressed the limited mandate of the EU in relation to issues such as the organisation of health services and patient access and clarified the difference between EU and Member State legal competences.

3. Cryos International provided a brief historical overview of their company, explaining that it had been established decades ago by its current Executive Director and that its primary aim is to help people to have children when it is difficult or not possible for them to do so naturally. It is now

the largest company of its kind in the world, supplying sperm to women in all EU Member States and beyond.

4. Cryos stated that access to (non-partner) donated sperm is the key challenge in Europe with many Member States not allowing the use of donor sperm or limiting access for certain population groups. According to Cryos, the demand has increased by around 500% over recent years, but only 10% of those who need access to medical treatment with donated gametes are receiving it. They noted that population growth in the EU has slowed down and that it is a priority that the rate of childbirth be increased; this objective would be supported by increasing access to donor sperm.

5. In the view of Cryos International, the access issue has been exacerbated by the adoption and implementation of the EU legislation which makes it too difficult for centres to comply. They noted that many sperm banks closed down after the legislation was adopted. The key barrier to compliance was identified by Cryos as the administrative burden imposed by the regulations which require the employment of staff dedicated to manage the required documentation.

6. Cryos also pointed to a varying approach to the interpretation of the legislation across different Member States as a strong barrier to distribution. Cryos will send examples to DG Santé.

7. In the view of Cryos, the EU should consider the demand and allow an open single market for sperm. They noted that in 2011 the Danish courts had ruled that sperm should be considered a 'good' and that value added tax should be applied. This was considered by Cryos as an indication that also the internal market rules should apply.

8. Cryos stated that it was already difficult to recruit adequate numbers of donors but that rules put in place by regulators, e.g. the dropping of donor anonymity in some Member States, had made this situation worse. At least one Member State was reported as not allowing distribution of sperm by Cryos on the basis that they have both anonymous and non-anonymous donors. They state that other Member States ban the import of gametes to their country from Denmark, even though the EU legislation defines this as 'distribution' (i.e. from a tissue establishment to an organisation responsible for human application) rather than 'import'.

9. The EU rules on traceability were considered by Cryos to be a hindrance to access and not to acknowledge the fundamental differences between sperm and other types of donated human substances. The interpretation of donor testing requirements in relation to donations already in storage, to vigilance reporting in cases of the birth of children that inherit genetic conditions from sperm donors and the interpretation of the requirements for third party agreements were also identified by Cryos as barriers to distribution.

10. In conclusion, DG Santé underlined the need to differentiate between rules which can be put in place by individual Member States and those which are the competence of the EU, asking the stakeholders to focus their comments on issues of relevance to the EU legislation in the context of the ongoing evaluation.