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), Cryos International and *Styrelsen for Patientsikkerhed*

8 November 2016

Draft Summary Minutes

Participants:

Cryos International

Styrelsen for Patientsikkerhed *(the Danish competent authority for tissues and cells)*

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

Cryos International (Cryos) had requested a meeting with DG SANTE (SANTE B4) following discussions in the Competent Authorities for Substances of Human Origin (CASoHO) Expert Group on the direct distribution of sperm to individuals and current plans in Denmark to amend national law relating to this.

1. After the introduction of the participants, SANTE B4 acknowledged that there had indeed been discussions in the CASoHO Expert Group meeting on direct distribution of sperm to private individuals as described in the summary minutes of such meetings. SANTE B4 stressed that Union legislation on tissues and cells is largely limited to quality and safety issues while ethical issues such as who has access to assisted reproduction and non-partner donor sperm are decided at Member State level. Cryos stated that the reason for its visit was to discuss quality and safety issues surrounding direct distribution of sperm to private individuals. Cryos added that, if the current Union legislation is interpreted as restricting direct distribution, it may actually have the opposite effect to the one intended and not ensure public health protection for recipients.

2. The *Styrelsen for Patientsikkerhed* (DK CA) confirmed that, following the public consultation, the Ministry of Health still planned to propose an amendment to Danish law which would prevent direct distribution of sperm to individuals while maintaining the right of individuals to obtain sperm directly from sperm banks as long as distribution is to an authorised tissue establishment, fertility clinic, hospital unit or authorised health care professional. A first discussion on this in the

Danish Parliament is planned for November 25th 2016 and the outcome will likely be known in spring 2017.

3. Cryos stated that it is evident that the Danish proposal would actually lead to less traceability and less patient safety. According to Cryos, its motive is to help individuals, in particular lesbians and single women, who, due to national rules in the Member States where they reside, do not have access to (non-partner) donated sperm. According to Cryos, if they are no longer able to obtain sperm from Cryos via direct distribution, these women might try to become pregnant through less safe means (the so-called "grey market" with medical, legal and social complications as a consequence) unless they travel to another country where access to assisted reproduction with donated sperm for such individuals is permitted. Only few can afford to do so.

4. SANTE B4 pointed out that it is up to each Member State to decide on who may access assisted reproduction and non-partner donated sperm and what it considers acceptable in terms of public health protection and ethics ("public policy"). Moreover, the authorities in each Member State need to be able to monitor compliance with its national rules, including ensuring the safe application of tissues and cells. Furthermore, the quality and safety standards in the Union legislation need to be respected and the practice of direct distribution of sperm to private individuals raises serious question marks as to how the requirements on, *inter alia,* traceability and serious adverse events and reactions can be met without the involvement of an organisation responsible for human application.

5. Cryos stated that it distributes to clients in all 28 EU Member States and that it has full traceability from donor to recipient and vice versa, a traceability system it has developed at considerable cost over a number of years. The preamble is, per definition, traceability to the recipient and not to any links in-between. Cryos assumed that delivery of cells directly to the recipient was probably just not foreseen when the directive was written. Cryos had provided a written statement outlining their position and reasoning prior to the meeting. SANTE B4 have yet not responded to this.

6. SANTE B4 questioned whether the system described by Cryos would meet the definition of traceability in the Union legislation which includes the *ability to identify the recipient(s) at the medical facility/facilities applying the tissue/cells to the recipient(s),*[1] given that a medical facility or healthcare professional is not (always) involved in the application of sperm following direct distribution to private individuals. Cryos commented that they would look into this.

   Nota Bene: An analysis has later been sent to SANTE B4 from Cryos stating that, in Cryos' view, the rules set out in the Directive are unclear and that the ability to applying is mentioned as an example and do not restrict distribution directly to recipients. Actually, the Directive states[12] *that distribution can only be to the recipient or to a tissue establishment. Medical facility/facilities, fertility clinic, hospital unit or authorised health care professionals are not included, unless they are licensed tissue establishments.)*

[1] Article 2(g), Commission Directive 2006/86/EC.
[2] Section 1.7.c and 2.1, Annex IV, Commission Directive 2006/17/EC

7. Cryos asked for more details of the analysis made by the Commission on whether the practice of direct distribution to private individuals is compatible with Union legislation on tissues and cells. It felt that the amendment to Danish law is a direct result of this and it would be difficult to defend the practice of direct distribution to private individuals without knowing the full details of the analysis. SANTE B4 explained that the conclusions of the analysis were available in the summary minutes of the CASoHO expert group meeting during which the conclusions were presented to the Expert Group. Furthermore, SANTE B4 explained that is was standard practice not to make the analysis itself available as the draft amendment to Danish law had not yet been adopted and further follow-up may be needed. SANTE B4 and DK CA confirmed that this analysis had not been made available to the Danish authorities or indeed to any other member of the CASoHO Expert Group.

8. Cryos restated its concerns on the proposed amendment to Danish law and that this may lead to less safety and explained that, given that it considers it has full traceability, hoped a solution could be found. SANTE B4 reiterated that even if full traceability is *de facto* achieved, *de jure* this does not appear to be the case where sperm is directly distributed to individuals and where there is no organisation responsible for human application, accountable for documenting the fate of the sperm and notifying any possible adverse outcome to the authorities. The Danish measure is designed to clarify this requirement in Danish law. Cryos stated that it would look into this (*See item 6 Nota Bene)*.

9. SANTE B4 pointed out that it is currently planning an Evaluation of the Union legislation on tissues and cells and that this exercise will look at, *inter alia,* whether the legislation is still fit for purpose over ten years after its adoption. SANTE B4 stated that this exercise will involve considerable consultation of stakeholders and encouraged Cryos to participate in this consultation of stakeholders.