

Further statements are also wrong and should be documented or immediately recalled:

“The mentioned offer is illegal in Spain as it seriously violates the Spanish law 14/2006 for assisted reproduction and the Royal Decree 9/2014 introducing the EU legislation”.

As Cryos is a licensed tissue establishment (license attached), it is also licensed to distribute in all EU-countries, including Spain. Thus, your statement is in clear conflict with this license, granted by the Danish Health Authorities.

It is not correct to affirm, as you do, that the mentioned offer is illegal according to the Spanish law 14/2006 for assisted reproduction, and the Royal Decree Law 9/2014.

Mainly, because these laws are not applicable for Cryos, who is a Danish entity/tissue establishment. The EU Tissue Directive or Danish regulation, which are those Cryos must apply to, do not mention to whom delivery shall take place or whom can be inseminated with the sperm or that treatment shall be performed assisted or not.

There are certainly different regulations in force nationally for assisted medical treatment, but as Cryos has no treatment at all, these rules are not applicable to Cryos.

Therefore, Cryos can legally distribute sperm to both private individuals and clinics all over EU.

Furthermore, these laws are not applicable for private persons in Spain, as they are not performing an assisted treatment when doing home insemination.

Regarding your four statements with reference to the specific legislation:

“1.- Performing any kind of techniques of assisted reproductive technique can only take place in clinics or health centres duly authorized by the competent health authority (Art. 4.1 of Law 14/2006). Only in this way can it be performed by competent professionals who can ensure that the treatment is appropriate and does not pose serious health risks to the patient or its progeny, and that it is practiced in the most proper way.”

However, this statement is incorrect as “home insemination” is unassisted, so the mentioned Spanish laws do not cover it.

“2.- Violation of anonymity requirement of donor gametes, which are designed to protect private life / the privacy for both donors and patients themselves (Art. 5.5 of Law 14/2006).”

Again, “home insemination” is unassisted, so the mentioned Spanish laws do not cover it.

You shall therefore document that the law are applicable for unassisted treatment, or otherwise recall your statement.

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"3.- Violation of the rule that it is the doctor / medical team that must choose the donor, which also guarantees that it is the most appropriate donor for the receiving couple (art. 6.5 of lov14 / 2006). The fact that patients choose donor characteristics, promotes trade of gametes, which goes against what is stated in the Spanish and European regulations."

Once again, "home insemination" is unassisted, and the mentioned Spanish laws do not cover it. We also request you to inform to which specific European Regulations you refer to. We can inform that Cryos does not sell the donor sperm, but the process, handling, testing, etc. cf. Cryos' [Terms of Agreement pkt. 25](#) (attached) and that this complies with a decision from the Danish Minister of Health.

"4.- From the moment, when samples of sperm are sent to patients' homes, traceability and biosecurity measures are no longer guaranteed, which are mandatory requirements throughout the European region and allows to reconstruct the origin of the cells, when there is a health problem (Decree 9 / 2014)."

This statement is not correct. Cryos maintains traceability cf. The EU-Tissue directive in 30 years from last use. This is the same whether Cryos delivers to a clinic, a tissue center or directly to the recipient, so we consider there is no lack of traceability and biosecurity at all.

We look forward to receive your documentation and the basis for all your statements, or an immediate official recall.

Finally, our client would be very happy to initiate a serious dialogue with you afterwards to clarify any potential questions you could have.

We are all part of the Spanish market, and will without doubt be so in the future, so it would be an advantage for all of us to get along and keep a good tone.

We look forward to receive your answer before next January 15, 2016, in order to reach an amicable solution of the matter.

Sincerely yours,

Juan Carlos Hernanz
Attorney