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Sundhedsministerens opfølgning på IU den 1. marts 2019 vedr. vævsdirektivet

Kære Paul

På møde i EU-Implementeringsudvalget (IU) den 1. marts 2019 behandlede vi afrapporteringen af et nabotjek om vævsdirektivet.

På baggrund af nabotjekket, der bl.a. viste, at der kan være tale om en uensartet implementering eller gennemførelse af direktivet, blev det besluttet, at sundhedsministeren vil påpege den uensartede implementering i et brev til Kommissionen.

Samtidig vil sundhedsministeren i et brev til vævscentret Cryos orientere om nabotjekkets resultat og sundhedsministerens henvendelse til Kommissionen.

Sundhedsministeren har nu afsendt sine breve til Kommissionen og Cryos, og jeg fremsender derfor som lovet i mit brev til IR den 14. marts 2019 brevene til jeres orientering.

Venlig hilsen

Troels Lund Poulsen

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Date: 22nd March 2019
Section: MEDINT
Case Officer: DEPCRV
Case: 1709273
Doc.: 854738

Mr Vytenis Andriukaitis
Commissioner for Health and Food Safety
The European Commission

Dear Mr Vytenis Andriukaitis

In 2018, the Danish Government initiated a review of practices in selected Member States of the implementation of the Tissue and Cells Directive.[1] The purpose was to uncover whether the definition in the Danish Act on Quality and Safety Regarding Human Tissues and Cells (Danish Tissues and Cells Act) of genetic disease in donor children as a "serious adverse reaction" (SAR) could be considered an unnecessary and unintended "gold plating"[2] of the Directive, cf. Art. 3 (n).[3]

As a part of the review the Ministry of Health compared the Danish definition of SAR with the definition and practice in five other Member States (Estonia, France, the Netherlands, Sweden and the United Kingdom).

The result was that the definition in the Danish Tissues and Cells Act generally corresponds to the *practice* in the before mentioned five other EU countries. All five countries, like Denmark, use rapid alerts as a platform to ensure that tissue establishments or fertility clinics have handled information about serious genetic disease in a foetus or a child conceived with the help of donor gametes (from another donor than partner) regardless of whether the requirement is due to legislation or practice.

However, the review also revealed that there may be a disparate implementation or use of the Tissues and Cells Directive in some of the Member States included in the review – and therefore probably also in other Member States.

In the national legislation or regulation of France, Estonia and the UK, as in Denmark, genetic disease in a donor child is considered a SAR. In the Netherlands and Sweden, however, the definition laid down by *law or regulations* of genetic disease depends on a medical estimate.

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[1] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

[2] "Gold plating" in this context characterises the process where an EU directive is given additional powers when being transposed into the national laws by Member States or an excess of norms, guidelines and procedures accumulated at national level which interfere with the expected policy goals to be achieved by such regulation.

[3] Article 3 (n): ""Serious adverse reaction" means an unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of tissues and cells that is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity;"

In my opinion, one of the main objectives of the Tissues and Cells Directive is to ensure that children conceived when using donor gametes are not born with serious genetic diseases that could have been avoided.

./. This point of view is supported by the enclosed minutes of the meeting of the Competent Authorities on Substances of Human Origin, cf. Annex 1. Here the Commission is reminding the Member States that, regardless of the specific nature of the Tissues and Cells Directive, genetic disease in donor children should be considered a SAR. The Commission also gives reference to specific EU and ECDC guidelines etc.

In order to maintain a high level of patient safety, it is of great importance that relevant European tissue establishments or a fertility clinics receive alerts regarding SARs for them to initiate an effective revocation procedure if it appears that genetic diseases occur in the donor and/or donor children.

Secondly, the recall of donor material, notification of donors and the issuance of rapid alerts to other Member States, where genetic disease in donor children might not be considered a SAR, is very resource-intensive for Danish companies in the industry, especially the Danish sperm banks.

On that basis, I respectfully ask the Commission to enforce a uniform implementation of the Directive ensuring that all Member States meet the same high level of safety for donor children which is intended in the Directive and the before mentioned guideline and statements from the Commission.

Furthermore, I kindly request that the Commission will include an adequate definition of SAR in the forthcoming revision of the Tissues and Cells Directive in order to obtain clarity and full alignment of Member States in the years to come.

Yours sincerely,

Ellen Trane Nørby

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Vedr. nabotjek af implementeringen af vævsdirektivets definition af alvorlig bivirkning

I januar 2018 besluttede Regeringens Implementeringsudvalg at følge Implementeringsrådets indstilling fra december 2017 om, at Sundheds- og Ældreministeriet inden udgangen af 2018 skulle gennemføre et nabotjek af implementeringen af vævsdirektivet i dansk ret.

./. Ministeriet gennemførte nabotjekket fra juni til december 2018, og afrapporteringen af nabotjekket blev behandlet på et møde i Implementeringsudvalget den 1. marts 2019. Til jeres orientering vedlægges et afrapporteringsskema fra nabotjekket samt relevant referat fra et teknisk møde i Kommissionen om problemstillingen.

./. Som det fremgår, har nabotjekket vist, at der kan være tale om en uensartet implementering eller gennemførelse af direktivet i de undersøgte lande, hvilket sundhedsministeren den 25. marts 2019 har påpeget i vedlagte brev til Europa-Kommissionen.

Med venlig hilsen

Camilla Rosengaard Villumsen