



## EAHL NEWSLETTER

The EAHL newsletter is published twice a year and is intended to provide the members an overview of selected developments within European Health Law (mainly from the European Union and the Council of Europe)

### European Union

#### **Council adopts new EU rules aiming for safer medical devices**

On 7 March 2017, the [Council adopted new EU rules](#) aiming at improving the safety of medical devices for the benefit of patients while preserving a timely access to innovative healthcare solutions. The new rules intend to keep pace with recent technical developments. Their scope has been extended to cover certain products which do not have a specifically medical purpose, such as coloured contact lenses. The reform consists of two new EU regulations: 1) Regulation on medical devices and 2) Regulation on in vitro diagnostic medical devices (which includes genetic tests). They will amend Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. The European Parliament is expected to adopt the two regulations in April, after which they will be published in the Official Journal. The new rules will apply three years after publication as regards medical devices and five years after publication as regards in vitro diagnostic medical devices.

#### **Report on the implementation of the “transplant directive”**

The commission has published [a report on the implementation of Directive 2010/53/EU](#) of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (COM(2016) 809 final). The report focuses on the institutional set-up in Member States, and in particular on the identification of the authorities in charge of the different tasks listed in Article 17 of Directive 2010/53/EU. The report also provides an overview of the consent systems in the Member States. Two main consent systems exist in Europe: an “opt-in” system under which donors are required to explicitly give their consent for organ donation, and an “opt-out” system.

#### **Report on the implementation of the “cross-border healthcare directive”**

Jonathan Olsson consulting has made a report for the Commission on [Member State Data on cross-border healthcare](#) following Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare. Only 23 replies were received. A majority of the Member States received less than 100 requests for prior authorisation during year 2015. The number of requests for reimbursement relating to healthcare not subject to prior authorisation was low (with Belgium and Denmark as exceptions).

#### **Call for applications ‘Health — 2017’**

A [call for applications](#) under ‘Health — 2017’ is launched within the framework of the third Programme of the Union’s action in the field of health (2014-2020). This call for applications consists of the following parts:

- a call for proposals for the award of a financial contribution to specific actions in the form of project grants,
- a call for proposals for the award of a financial contribution to functioning of non-governmental bodies (operating grants)

Deadline for Deadlines for online submissions of the proposals are 15 June 2017.

## Council of Europe

### Legislation

The committee of ministers has issued a [recommendation](#) on the processing of health-related data for insurance purposes, including data resulting from genetic tests (CM/Rec. 2016(8)). The recommendation states that the object is that Member States should take “appropriate measures to ensure respect for the fundamental rights of persons, without discrimination, in the context of the insurance contracts covered by this recommendation”.

### Decisions by the European Court of Human Rights

The Grand Chamber of the Court made their judgment in [Paradiso and Campanelli v. Italy](#) (Appl. No., 25358/12 judgment 25 January 2017). The case concerned an Italian couple who went to Russia and entered into a surrogacy agreement after unsuccessfully waiting for adoption in Italy (the couple were approved for adoption). After return to Italy, the Italian authorities came aware of the surrogacy agreement, and when the child was nine months old when it was taken into custody by the child care services. The child was later adopted to a new family. The majority of the Grand Chamber (eleven votes to six) came to the conclusion that there was an intervention in the private life of the applicants, but that the interference was necessary in a democratic society. The protection of family did not apply since there were no genetic connection between the parents and the child.

The Grand Chamber of the Court made their judgment in [Dubská and Krejzová v. the Czech Republic](#) (Appl. Nos. 28859/11 and 28473/12, judgment 15 November 2016). The applicants complained that Czech law did not allow health professionals to assist them with giving birth at home, was a violation of the right to private life as provided for in Article 8. The Grand Chamber found that it was an interference with the applicants’ right to avail themselves of the assistance of midwives when giving birth at home, owing to the threat of sanctions for midwives, who in practice were prevented from assisting the applicants by the operation of the law. However, the interference had sufficient basis in national law, fulfilled a legitimate aim and was found to be necessary in a democratic society. A minority of the Grand Chamber (five judges) found that the relevant Czech legislation renders home births de facto impossible given that creates excessively rigid requirements, thus constitutes an interference with mothers’ freedom of choice that is not proportionate in a democratic society.

[Otgon v. Moldova](#) (Appl. No. 22743/07, judgment 25 October 2016) concerns limited compensation after having drinking contaminated water delivered by a State-owned local utilities provider. The applicant was hospitalised for two weeks after the incident and later successfully claimed compensation. However, the applicant held that the award (50 000 Moldavian Lei, approximately 650 Euro) made in her favour had been too small to compensate for the physical and mental suffering caused to her and her family. The Court found that an interference with the applicant’s rights protected under Article 8 had taken place since her physical integrity has been affected by an unhealthy environment. In assessing whether the Moldovan authorities had discharged their positive obligation under Article 8, the Court considered that the sum awarded by the domestic courts is considerably below the minimum generally awarded in cases concerning Moldova where a violation of Article 8 had taken place (dissent 6-1).

[Vasileva v. Bulgaria](#) (Appl. No. 23796/10, judgment 16 March 2016) concerns the alleged lack of impartiality of medical experts in proceedings relating to medical malpractice. After a surgery to remove suspected metastasis in the chest, the applicant suspected that the surgeon who had operated on her had removed fragments of the wrong ribs during the surgery. Her claim for compensation was unsuccessful. The Court took as point of departure that it is now well established that although the right to health is not as such among the rights guaranteed under the Convention, the states have a positive obligation under Article 8, firstly, to have in place regulations compelling both public and private hospitals to adopt appropriate measures for the protection of their patients’ physical integrity and, secondly, to provide victims of medical negligence access to proceedings in which they could, in appropriate cases, obtain compensation for damage. The Court emphasized the broad margin of appreciation enjoyed by the states in laying down their health care-policy. When the states were to choose how to comply with their positive obligations and organise their judicial systems, there is no basis on

which to hold that the Convention requires a special mechanism which facilitates the bringing of medical malpractice claims or a reversal of the burden of proof.

The Court has also decided several cases under Article 5 concerning deprivation of liberty within health law, see inter alia [Červenka v. the Czech Republic](#) (Appl. No. 62507/12, judgment 13 October 2016) regarding involuntary placement in a social care institution (violation) and [Petschulies v. Germany](#) (Appl. No. 6281/13), judgment 2 June 2016) concerning long term preventive detention of a patient of "unsound mind" with violent behaviour (no violation).

The website of the Court also contains [factsheets](#) providing compilation of case-law in various fields, including health (and see also the new factsheet on gestational surrogacy).

## European Journal of Health Law

The latest issue of the [European Journal of Health Law](#) (No. 1 2017) contains the following research articles:

- Gabriella Berki, Lightning or Lightning Bug: The Role of the Language Gap and the Access to Proper Information on Entitlements in Cross-border Patient Mobility (pp. 1–23)
- Neil Maddox, Property, Control and Separated Human Biomaterials (pp. 24–45)
- Geneviève Michaux, Should Anthroposophic Medicinal Products Be Regulated in Europe? (pp. 46–66)
- Mary Donnelly, Developing a Legal Framework for Advance Healthcare Planning: Comparing England & Wales and Ireland (pp. 67–84)

## Others

OECD Health Ministers welcomed the [Recommendation of the OECD Council on Health Data Governance](#) at their meeting in Paris on 17 January 2017. The Recommendation lays out the framework conditions to encourage greater availability and processing of health data within countries and across borders for health-related public policy objectives, while ensuring that risks to privacy and security are minimised and appropriately managed.

A [report has been made to the WHO](#) on “Advancing the right to health: the vital role of law”. The report aims to raise awareness about the role that the reform of public health laws can play in advancing the right to health and in creating the conditions for people to live healthy lives.

## NEXT EAHL Conference

The 6th EAHL conference will be held in Bergen, Norway 28-29 September 2017. The conference is now open for registration; please visit <http://eahl2017.org/> for more information, registration and submittal of abstract. A PhD seminar will be held 27 September and PhD students can apply for funding of the seminar and the conference (more information on the website).