

## Message of the President



EAHL President  
Prof. Dr. Karl Harald Søvig

Dear EAHL members,

I hope that you all have had a peaceful Christmas celebration, and that the beginning of 2019 has been fruitful. One of the major activities of EAHL is the biannual conference. The 7th EAHL conference will be held 25th to 27th September in Toulouse, and this newsletter is to a large extent dedicated to this event. I hope to see many of the members at the conference.

As some of you may be aware of, a committee has been appointed to reflect upon the most appropriate future EAHL activities and their set up. The report is available at the EAHL website (please insert a link) and many of the suggestions will be followed up by the board.

The board has been working with the design and content of the EAHL website. We have launched a refreshed website. Hopefully, the new website will facilitate more activity amongst EAHL members and provide useful information for the members. The board normally meets by Skype, but held a physical board meeting in Brussels in December, where we also met representatives from the Europa Commission.

The Newsletter is dependent on contribution from the EAHL members. All suggestions for material and improvements can be submitted to [eurohealthlaw@gmail.com](mailto:eurohealthlaw@gmail.com).

Best regards,

Karl Harald Søvig

## Newsletter

January, 2019  
Issue No 1

### CONTENT

1. Message of the President.....1
2. Next EAHL Conference.....2-3
3. Council of Europe workshop in 7th EAHL Conference .....4
4. Upcoming events and News...5
5. Big Data in the Pharmaceutical Sector between Protection and Transparency: Opportunities and Legal Challenges.....5-6
6. Healthcare Disparities disruptive healthcare technologies and the patient.....7-8
7. “28th Medicine, Law and Society” Conference.....9-10
8. Jean Monnet MOOC on “EU integration and ethics” .....9
9. About new Health Law Centre. Alt Lund University.....11
10. Legal news and recent case laws from Slovenia.....12-13
11. Publications.....14
12. Contact us.....15

# EAHL next conference



Dear EAHL members

Thanks to the efforts of our partners and of the scientific committee, the preparation of the 7th EAHL Conference Toulouse France 25 -27 September 2019 is progressing very well. The theme chosen “Innovation & Health Care: New Challenges for Europe” has attracted a great deal of interest from members of the Association, Academics in Europe and International Organizations, especially the Council of Europe (CoE). We obtained the CoE Patronage, the Conference is organized under the auspices of the CoE Secretary General.

To day, three **keynotes speakers** have already confirmed their participation. **Dr. Laurence LWOFF**, Head of Bioethics Unit in the Council of Europe Human Rights Directorate will talk on “New technologies: new challenges for human rights? The work of the Council of Europe”. **Pr. Henriette ROSCAM AB-BING**, past President of the EAHL, will present “Innovative technologies, a challenge for equal access to health care in Europe”. The topic chosen by **Pr. Judit SANDOR**, Central European University (CEU) of Budapest is “Human genome editing: what are the legal Implications for Europe and for the world?”. More Keynote speakers are expected.

**The call for abstracts** is open and we warmly thank the EAHL members who already send their abstracts. The topics are : Innovative medicine; Innovative health and research; Innovative health care and rights of the patient; Access to health care and innovation; E-Health and data protection; Intellectual property; Innovation in health care with aging population; Empowerment and involvement of patients in innovative health care; Links with ethics and law in innovation...All the selected abstracts will be scheduled in parallel sessions, organized by topics.

# EAHL next conference

**Workshops:** Several partners proposed to organize workshops for specialists of a specific theme. Seven workshops have already been accepted. They are :

COE-HELP “The Council of Europe Education programme on Human rights (HELP) and bioethics”;  
“European Health Law and Innovation: substantive aspects and embedding in national legal orders”;  
“Health risk management in the European Union”;  
“Innovation and health care, a challenge for human/patient rights in Europe”;  
“Innovative medicine and research: ethical, legal and regulatory issues”;  
“Is Intellectual property a booster or a hurdle for the health care innovation?”;  
“Rights on Health data and data bases”.

Further workshop proposals can be submitted.

**The PhD Seminar** is planned on September 25th for students or young scientists (under 35). Posters or oral presentations may be in English or in French. Topics are those of the conference and moreover contemporary approaches to health law. Please visit the web site for guidelines of abstract submission (deadline March 1st). The best oral presentation and the best poster will be selected for awards. Candidates should register to attend all the events of the conference (75 euros). Special housing is possible (51 euro per night). Free registrations will be offered to PhD or young scientists of the partners of the conference.

**Social programme :** A cocktail reception will be given by the Mayor at the Capitole (City Hall) on September 25, at 18h30 to all the attendees. For those who chose this option, the gala dinner will be held on the 26th at the Château de Marville. Other optional events are proposed if 30 participants register.

**Important dates :** Abstract submission deadlines: March 1st for PhD Seminar. May 19 for other abstracts

**Further steps :** Several partners are still planning to propose workshops or specific sessions. Depending on the abstracts submitted, adjustments in the program will be made. A special secretariat will be set up to facilitate direct exchanges on scientific aspects of the organization and links with partners.

We strongly encourage EAHL members to promote the conference in their networks in Europe and abroad. Do not hesitate to contact the members of the organizing and the scientific committees as well as the workshop coordinators for more information. Your suggestions are welcomed. This conference is yours!

On behalf of the organizing committee

Anne-Marie Duguet

Contact : [aduguet@club-internet.fr](mailto:aduguet@club-internet.fr)

Conference Web site : <https://eahl2019.sciencesconf.org>

## COUNCIL OF EUROPE WORKSHOP in 7<sup>th</sup> EAHL Conference

### ***“The Council of Europe Programme for Human Rights Education for Legal Professionals (HELP) and Bioethics”***

Evolution of biology and medicine, including new technologies, has produced spectacular advances in the health field. However, these developments raise ethical issues that affect the individual and the protection of the individual's rights and dignity. Furthermore, the widespread use of information and communication technologies also in the medical sector can imply data protection violations.

Several legal instruments (binding and non-binding) have been adopted within the Council of Europe human rights protection system. In 1997, the Convention on Human Rights and Biomedicine (Oviedo Convention) was adopted and further complemented by Additional Protocols on specific subjects. These legal instruments have been used as reference by the European Court of Human Rights in an increasing number of cases.

The right to privacy and personal data are protected both by the legal instruments developed by the Council of Europe (CoE) and the European Union (EU). The EU Charter explicitly mentions in Article 8 the right to data protection, considering it as a fundamental right in itself. Nevertheless, the two rights – privacy and data protection- are not absolute and may be subject to limitations. Any restrictions with regard to these rights must be made in accordance with the law, pursue legitimate aim(s) and be necessary in a democratic society.

To enhance training in these fields, the Council of Europe developed the European Programme for Human Rights Education for Legal Professionals (HELP), a comprehensive curriculum on various human rights related topics. These high quality and tailor made online courses aim at assisting mainly legal and health professionals, as well as persons working in the field of data protection and privacy rights, in effectively applying the European human rights standards in their daily work. Topics are explored in a practical way, by using videos, interactive screens, case presentations, knowledge tests and reflective exercises.

A workshop presenting the COE-HELP training programme will be hosted by the next European Association on Health Law (EAHL) Conference, that will take place in Toulouse (25-27 September 2019). This workshop is organised under the coordination of Ana Medarska-Lazova, HELP Project Officer, Katrin Uerpmann, Administrator/lawyer of the Bioethics Unit and Laurence Lwoff Head of the Bioethics Unit. It will focus on HELP courses related to key human rights principles to be applied in the field of biomedicine that have been developed with the CoE Bioethics Unit as well as on data protection.

After an introduction of HELP courses and methodology, an overview will be provided of the key human rights principles in biomedicine. Free and informed consent, medical confidentiality and protection of health-related data will be addressed. Further, the application of these key principles in specific contexts (biomedical research and genetic tests) will be analysed.

Finally, a course on data protection and privacy rights will be presented focusing on health-related issues and referring to the legal framework of the CoE and the EU as well as of the relevant jurisprudence.

The workshop will be chaired by Laurence Lwoff, Head of the Bioethics Unit of the Council of Europe and by Annagrazia ALTAVILLA, Lawyer specialised in European Health Law and Bioethics, as EAHL French representative.

On behalf of the organizing committee  
Annagrazia ALTAVILLA

For further details and the scientific programme, please see the conference website: <https://eahl2019.sciencesconf.org>

Contact : Annagrazia ALTAVILLA [annagrazia.altavilla@free.fr](mailto:annagrazia.altavilla@free.fr)

## UPCOMING EVENTS & NEWS

The European Parliament has received a report on the implementation of the Cross-Border Health Care Directive. The report intends to analyse the current shortcomings in the implementation of the Directive and to make recommendations for the improvement of the Directive.

<http://www.europarl.europa.eu/sides/getDoc.do?type=REPORT&reference=A8-2019-0046&format=XML&language=EN>

FEBRUARY 27, 2019



Universität  
Basel  
Juristische  
Fakultät



### **Big Data in the Pharmaceutical Sector between Protection and Transparency: Opportunities and Legal Challenges**

27 February 2019 | Basel | [Registration Form](#)

Data in the healthcare and pharmaceutical sector play an important role in various aspects. Data has already transformed many facets of the sector. Huge datasets are driving new drug discoveries and are making clinical trials more efficient. Wearable devices such as sleep trackers are creating more informed patients and the employment of more sophisticated data models has enabled healthcare professionals better to predict and prevent illness. From personalised medicine to AI assisted diagnostics and genetic engineering and sequencing, the possibilities, it seems, are endless.

However, despite its potential to improve patient care and the share price of pharmaceutical companies, legal and regulatory challenges remain. One need to look no further than the recent introduction of the General Data Protection Regulation (GDPR) to realise that significant regulatory challenges exists. With patients and regulatory becoming increasingly cognizant of data protection issues, regulatory restrictions are only going to increase.

one-day conference is specifically designed to help you navigate these challenges and recognise opportunities. Aimed at practitioners, regulators and academics alike, this event will help to avoid legal pitfalls and embrace opportunities as the healthcare sector enters into the era of big data.

The [programme](#) includes discussions on:

- Transparency and Consent in the Era of Big Data Analysis and Personalized Medicine
- AI and Pharma: Ethical Issues and the Problem of Bias
- AI, Protection and Ownership of Pharmaceutical Data
- Blockchain and Data Sharing in the Pharmaceutical Sector
- Regulatory Challenges and Opportunities in the Age of Big Data

Speakers will include:

- **Nikolai Brun**, Chair of the HMA/EMA Joint Task Force on Big Data and Director of Division of the Medical Evaluation & Biostatistics Division (Danish Medicines Agency)
  - **Prof. Dr. Claudia Seitz**, Faculty of Law, University of Basel, Center for Life Sciences Law (CLSL)
  - **Prof. Dr. Joaquin Cayon De Las Cuevas**, University of Cantabria
  - **Maria Chiara Atzori**, Head of Data Privacy Novartis International AG
  - **Marieke Jansen**, Head of Legal C&G Europe, Novartis
- ⇒ **Prof. Dr. Timo Minssen**, University of Copenhagen

**EAHL members are offered 10% discount at registration to the event.**

# HEALTHCARE DISPARITIES disruptive healthcare technologies and the patient

13th - 15th June 2019

The question of health inequalities worldwide has become increasingly significant and there is now a wide range of active researchers from a variety of disciplines working in this field. This conference is intended to bring these people together for the first meeting of what is hoped will be an ongoing global academic network.

The conference is sponsored by the Hallsworth Endowment and the School of Law at the University of Manchester. Collaborative institutional support is provided by Queen Mary, University of London with further support from the European Association of Health Law and the World Association of Medical Law. The conference will combine keynote and breakout sessions.

Pre-conference PGR workshop for postgraduate students: Wednesday 12th June 2019. Details about this event are available from Ajmal Mubarik ([ajmal.mubarik@postgrad.manchester.ac.uk](mailto:ajmal.mubarik@postgrad.manchester.ac.uk)).

The conference dinner will be held at Christies Bistro, University of Manchester, Oxford Road, M13 9PL on Friday 14th June 2019. This is not included in the conference fee.

A wine reception, included in the conference fee, will be held in the Schuster Building, University of Manchester on Thursday 13th June 2019 from 7pm – 9pm.

Accommodation at The Crowne Plaza, Oxford Road, has been secured at a reduced rate of £112 for the room per night and £10 for breakfast. We have a limited number of hotel rooms for delegates and places will be allocated on a first come first serve basis.

For more information visit <https://www.law.manchester.ac.uk/connect/events/healthcare-disparities/>

Or scan the QR code:

*Schuster Building, The University of Manchester, M13 9PL*

*Abstract submission: 31st January 2019*

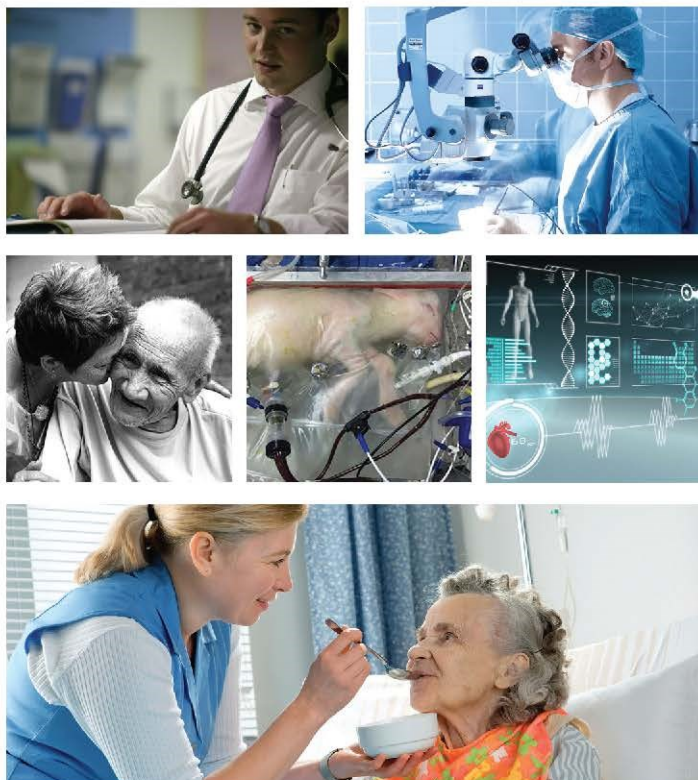
*Poster submission: 1st May 2019*

*Cost: £200 (Registration closes: 15th May 2019)*

*Early Bird Registration: £175 (Early Bird Registration closes 1st April 2019)*

*PGRs/ECRs/Members of WAML and EAHL: £150*





# HEALTHCARE DISPARITIES

disruptive healthcare  
technologies and the patient

**13th - 15th June 2019**



## Keynote Speakers

### **Professor Nicolas Terry**

Hall Render Professor of Law,  
Executive Director of the William  
S. and Christine S. Hall Center  
for Law and Health, University of  
Indiana, USA

### **Professor Ian Freckleton**

Melbourne Law School,  
University of Melbourne,  
Australia

### **Professor Tamara Hervey**

Jean Monnet Professor of  
European Union Law, University  
of Sheffield, UK

### **Professor Mette Hartlev**

University of Copenhagen,  
Denmark.

### **Professor Richard Ashcroft**

Queen Mary, University of  
London, UK

## OTHER EVENTS

### **“28th Medicine, Law and Society” Conference**

Main organizer: Faculty of Law, University of Maribor

**Topic:** “Globalization of Medicine in 21st Century”

**Subtopics:**

- Medical, legal, sociological and ethical view of biomedicine
- Artificial intelligence and robots in medicine

Date: 28th and 29th March 2019

**Venue:** Maribor, Slovenia

Languages: Slovene, Croatian, English

**Info:** [journal.mls@um.si](mailto:journal.mls@um.si)

**Website** of the conference: <https://www.pf.um.si/en/acj/events/>

---

### **April 8th – 19th, 2019**

Jean Monnet MOOC on “EU integration and ethics”

From April 8th – 19th, 2019

**Topics**

surrogacy | free access also for external participants

All relevant information can be found at [https://jeanmonnet.mci.edu/jean\\_monnet\\_mooc](https://jeanmonnet.mci.edu/jean_monnet_mooc)



Univerza v Mariboru

Pravna fakulteta

University of Maribor  
Faculty of Law – Centre for medical law  
Lawyer's Association Maribor and Medical Association Maribor

### FIRST CALL FOR PARTICIPATION IN

28th conference

**MEDICINE, LAW AND SOCIETY:  
“Globalization of Medicine in 21st Century”**

Maribor, 29th and 30th March 2019  
University of Maribor, Slomškov trg 15, 2000 Maribor, Slovenia

28th conference Medicine, Law and Society continue a long tradition which brings together highly esteemed and recognized domestic and foreign lecturers. With willingness and aim for analysis and discussion regarding open questions in medicine, law and society is prepared multidisciplinary topic:

### **Medicine, Law and Society: “Globalization of Medicine in 21st Century”**

Following the open legal, medical and ethical dilemmas and contemporarily guidelines and findings in the field of medicine will 28th conference focus especially on subsequent subjects:

- a) Medical, legal, sociological and ethical view of biomedicine:
  - i. research of genome;
  - ii. research on human embryonic stem cells;
  - iii. therapeutic cloning;
  - iv. biobanks and researches;
  - v. transplantation and regenerative medicine.
- b) Artificial intelligence and robots in medicine:
  - i. the future of artificial intelligence and its impact on human;
  - ii. are we prepared to be examined by robot doctor;
  - iii. robot – intermediary between physician and patient;
  - iv. robot – intermediary between nurse and patient;
  - v. robots – determination of legal status.

Important dates:

- a) 1st December 2018: summary submission (up to 500 words);
- b) 10th December 2018: notification of selected contributions;
- c) 15th January 2018: submission of final contributions;
- d) 29th and 30th March 2019: conference.

For any additional questions, please contact phone number ++386 2 250 42 32 (Associate Professor Suzana Kraljić, Ph.D.) or e-mail address: [journal.mls@um.si](mailto:journal.mls@um.si)

## About new Health Law Centre

In the fall of 2018, the Health Law Centre was founded at the Faculty of Law at Lund University. Professor Titti Mattsson is the coordinator for the Centre, and together with 15 researchers at the Faculty a wide range of research is being done and more is planned for the next coming years. This initiative has been possible thanks to generous funding by the Crafoord Foundation and the Faculty of Law at Lund University.

The Health Law Centre at the Faculty of Law at Lund University has during 2018 partaken in several conferences and hosted multiple seminars, including among others: Ass. Prof. Ted Dove of the University of Edinburgh on *Regulating Health Research in the UK*, Ass. Prof. Ana Nordberg of Lund University on *AI in a Swedish Context* and Ass. Prof. Anna Nilsson of Lund University on *Compulsory Mental Health Interventions and the CRPD*.

An international conference on Children's health matters in custody conflicts was held in November. During 2018/19 two guest professors from Norway are joining the team.

To stay up-to-date on the Health Law Centre's activities, please visit the [homepage](#). Those interested in the activities at the Centre or further information are always welcome to contact Titti Mattsson at [titti.mattsson@jur.lu.se](mailto:titti.mattsson@jur.lu.se).



Health Law  
CENTRE

## *News in legislation of Slovenia:*

- adopted November 2017 / applied since December 2017 - Act Amending the Health Services Act (Uradni list RS, št. 64/2017)
- adopted September 2017 / applied since January 2018 – Act Amending the Patients' Rights Act (Uradni list RS, št. 55/2017).
- adopted March 2017 / applied since April 2019 – (New) Family Code (Uradni list RS, št. 15/2017) – includes new legal regulation also related to the health issues (children; no more deprivation of legal capacity for the guardianship for adult persons ...).
- Rules on traineeships and professional examinations for healthcare and allied professionals in healthcare activities (Uradni list RS, št. 47/18)

\*All named law novelties have been adopted already in 2017. Additional new Rules on traineeships and professional examinations for healthcare and allied professionals in healthcare activities (published Uradni list RS, št. 47/18).

## **Recent Case law (Slovenia)**

### **a) VSRS sodba II Ips 290/2017 (ECLI:SI:VSRS:2018:II.IPS.290.2017), 17.5.2018**

*»As a general rule, the doctor must take into account the right of the patient to decide on oneself based on adequate information on the relevant facts relating to the medical intervention. This patient's right is protected under the Constitution of the Republic of Slovenia (CRS); Article 35 of the CRS guarantees to everyone the inviolability of human physical and mental integrity, privacy and personality rights. The inviolability of mental integrity means, in particular, the prohibition of interference in freedom of decision-making, the right to self-determination is emphasized, the right to decide for oneself. At the legal level, however, this right, which gives the patient the status of the subject in the treatment process, is protected under Article 47 of the Health Services Act (HSA), which, among other things, gives everyone the right to consent to the proposed medical intervention or to reject it.*

*Since the plaintiff's first birth was done with a cesarean section, the plaintiff found himself at the time of the birth of the first plaintiff in a situation in which the medical profession gave her the right to take an active part in the choice of the mode of birth, including the right to choose a child with a cesarean section. According to the established medical standards, she was therefore right to require the doctor to perform the labor with Caesarean section. Because her request was rejected with the explanation that they would first try natural birth, she was deprived of the possibility of deciding on herself. It was unduly included in its fundamental and at the same time the personal right to self-determination, which is protected in Article 35 of the CRS and Article 47 of the HSA.*

**b) VSL sodba II Cp 2229/2017 (ECLI:SI:VSLJ:2018:II.CP.2229.2017), 7.2.2018**

*When assessing the care of a doctor, professional and occupational standards, perceptions and behaviors that are valid in the medical field must be taken into account at the time the intervention is performed. The patient's consent to the procedure must be genuine and free, and the condition for this is the knowledge of the situation, that is, the patient's awareness of his condition and treatment options. The scope of the explanatory duty depends on the circumstances of the individual case and includes an explanatory diagnosis, a therapeutic explanation, and a risk explanation. In order for a patient to decide whether to consent to the procedure, he / she should inform the doctor about all the circumstances and options. Failure or fulfillment of the explanatory duty is irrelevant, compensation is of paramount importance when the associated risk is incurred, which the patient was not warned of, should have been and if a legally recognized injury was generated from such a realized risk.*

# PUBLICATIONS

⇒ *Competition Policy in Healthcare - Frontiers in Insurance-Based and Taxation-Funded Systems* has been published on 11th January 2019. Author: [Mary Guy](#)

Details are available here:

<https://intersentia.com/en/competition-policy-in-healthcare.html>

20% discount for EAHL members with code 'CPHC18'.

Offer cannot be used in conjunction with any other offer. Discount code expires 4th February 2019.

⇒ Frischhut, M. (2019, forthcoming). *The Ethical Spirit of EU Law*. Cham: Springer International Publishing. <https://www.springer.com/de/book/9783030105815>

⇒ Pirs, M., & Frischhut, M. (2019, forthcoming). *Ethical Integration in EU Law: The prevailing normative theories in EGE opinions*. In N. Ryder & L. Pasculli (Eds.), *Corruption, Integrity and the Law: Global Regulatory Challenges*. Milton Park, Abingdon, Oxon, New York, NY: Routledge.

⇒ KRALJIĆ, S., REBERŠEK GORIŠEK, J. & RIJAVEC, V. (eds.) (2018) 27. Posvetovanje Medicina , pravo in družba, 23. - 24. marec 2018, Maribor, Slovenija. *Sodobni izzivi in dileme : konferenčni zbornik* (Collection of papers: Medicine, Law & Society : Contemporary challenges and dilemmas). 1. izd. Maribor: Univerzitetna založba Univerze, 2018. IV, 358 pages, ilustr. ISBN 978-961-286-147-6, doi: 10.18690/978-961-286-147-6. (language: Slovene, Croatian, English).

⇒ ŽNIDARŠIČ SKUBIC, V. (2018) *Civilno medicinsko pravo: izbrane teme* (Civil medical law – selected topics). 1. natis. Ljubljana: Uradni list Republike Slovenije, 2018. 183 pages. ISBN 978-961-204-641-5. (language: Slovene)

⇒ KRALJIĆ, S. (2018) *Koja pravna pitanja otvara uporaba robota u medicini? (What legal issues opens using the robots in medicine)?*. V: CERJAN, Snježana (ur.). *Aktualna pravna problematika u zdravstvu*, XI. kongres pravnika u zdravstvu s međunarodnim sudjelovanjem, Varaždin, 19. - 20. listopada 2018. godine, (Actual legal questions in health care – XI. conference of lawyers in health care), ISSN 1847-7739, 2018). Varaždin: Udruga pravnika u zdravstvu. 2018, str. 65-80. (language: Croatian).

⇒ KRALJIĆ, S. (2018) *Medicinska sestra in sodno izvedenstvo* (Nurse and court expertise). V: KADIVEC, Saša (ur.). *Zbornik prispevkov, Strokovno srečanje Izzivi managementa zdravstvene nege danes za boljši jutri*, Maribor, 24. maj 2018. (Collection of papers: conference Challenges of nursing management – today for better tomorrow), Ljubljana: Zbornica zdravstvene in babiške nege Slovenije - Zveza strokovnih društev medicinskih sester, babic in zdravstvenih tehnikov Slovenije, Sekcija medicinskih sester v managementu. 2018, str. 10-16. (language: Slovene).

## EAHL

---

Membership of the EAHL is open to health lawyers in Europe.

To become a member of the EAHL, please, send your electronic application to **[eurohealthlaw@gmail.com](mailto:eurohealthlaw@gmail.com)**

EAHL secretariat organizes decision on admission and informs applicants about further procedure.

For more information, please, visit:

**<http://www.eahl.eu/membership>**

### *\*Note*

*EAHL Members are kindly invited to proceed 2019 membership fee payment.*

*Contact us if you need an invoice.*

EAHL has launched Twitter and LinkedIn accounts!

Follow us on Twitter <https://twitter.com/EAHLaw>

Join our network on [LinkedIn](#)

