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Block 4

Title 'Course guide EU Global Health Law 2017-2018

Syllabus

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1. Introduction

Welcome to the elective course European Union (global) health law. This manual will inform you about the course details including rationale, structure, literature and assessment. I hope you will enjoy the course and improve your knowledge on and understanding of EU health law.

Nowadays, the European Union and health are inextricably related. Under the current treaty, the 'Treaty on the Functioning of the European Union' (TFEU), the Union and member states have shared competences in the area of common safety concerns in public health matters, and the Union is required to take health protection into account in all its policies. But the most explicit health commitment has been made by the public health provision, article 168(1) 'A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities', followed by more specific Union competences in this area.

The history of the Union's health policy can be characterized as a "creeping competence". Since its establishment (1952) the role of the European Union in the field of health has gradually grown in terms of competences, and has become more explicit. Prior to the Treaty of Maastricht (1992) health regulations were merely based on agricultural policy, medicines and food safety and the internal market (public health exemptions on free movement and coordinating social security issues). Confronted with border-crossing health threats (HIV/AIDS, SARS, BSE, bioterrorism, etc.), the Maastricht Treaty, introduced a specific treaty-based competence aimed at health protection (article 129). During subsequent treaty revision, Union public health competences have gradually increased including standard setting of quality and safety of organs and substances of human origin, blood products and blood derivatives, adopting measures to combat major cross-border health threats, and fostering cooperation with international organizations like the World Health Organization and third countries in the sphere of public health.

As formal Union competence in the field of public health developed, whether or not combined with the general harmonization provision (art. 114 TFEU), newly established entities such as the European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC), and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), became responsible for respectively, the protection of human health through the evaluation and supervision of medicinal products, fighting infectious diseases, and providing information for drawing up informed drug laws and strategies. These, and other agencies, have an impact on the way the Union protects the health of its citizens, and supports its large health industry.

Conceptualising Union health competences, the main focus is on article 168 TFEU. Though understandable, this is however not the entire story. Other legal bases have also been lawfully applied to ensure a high level of health protection (eg, free movement provisions, consumer and environmental protection, social policy, competition policy, etc). For instance, under the consumer protection policy, the general product safety directive (2001/95/EC) established general safety requirements for all consumer products, including medical devices. Combined with the 'horizontal' liability directive for defective products (89/374/EEC), both directives are aimed to protect consumers' (patients') health against defective products. Additionally, Union social and employment law - aimed at protecting workers and fighting discrimination - had some unintended consequences in health care settings. A clear example is the Working Time Directive's applicability to medical professionals, which it is claimed has hampered the planning and organization of medical care. Furthermore, the coordination of social security law, the mutual recognition of diplomas of regulated health professions, combined with the harmonization of pharmaceutical law, as well as the impact of European competition law, have a clear health dimension. At the same time we will be confronted with new challenges since the Union is becoming increasingly involved in human rights and health care. The recently endorsed EU Charter of Fundamental Rights and newly established Human Rights Agency may influence EU law on health and health care in the member states. For instance, courts may consider the Charter as the basis of judicial review of the activities of EU institutions. Relevant rights may include the right to life, equal access to health care, human integrity, and informed consent.

Given the increased role of Union measures protecting health, and in line with the rationale of the internal market, extending such an approach towards a European health care market may seem quite logical. However, under the current Treaty provision article 168(7) that idea has been explicitly rejected "Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care..." Even the recently adopted directive on patients' rights in cross-border health care does not change this, although this directive does define common principles and standards on quality and patients' rights (eg, values of universality, access to good quality care, equity, and solidarity, eligibility criteria, informed choice, personal data protection, measures for seeking remedies, etc). However, the most essential elements (material scope, benefit package ('basket of care') and reimbursement decisions), remain the exclusive competence of the member states. As a consequence 'health will continue to be a highly constrained area of EU competence. Nevertheless, health law is firmly on the map as an area of Union competence.

André den Exter
Course coordinator

2. General information

2.1 Course objectives

This course will contribute to promote excellence in teaching and equip students with knowledge of European integration and health law. So far, a separate course on EU integration and health law covering a full range of health (related) topics on European integration is missing. Instead, the fragmented legal approach only addresses certain elements of EU law and health. By developing an extensive and unique teaching program of 96 hours this course will focus on the entire spectrum of EU health law, enabling teachers and students to invest in a relatively unknown area of European integration.

The course provides a comprehensive overview of the EU legal framework relevant to health and conveys an understanding of the history and development the health acquis with respect to public health, the free movement of patients, health professionals, health products and services, data protection, competition law in health care, the EU Human Rights Charter, and EU health law in a global/regional perspective, exploring the content of bilateral relationships with international organisations such as the World Health Organisation, World Trade Organisation and accession/3rd countries.

On completion of the course the participant will have a broad knowledge within the EU legal framework. Furthermore, the course will enable participants to understand, apply and analyse EU health legislation, related to relevant cases/topics, more specific this course aims at:

- Increasing new knowledge of the European legal framework on EU health law
- The student will be able to identify, analyse and understand contemporary legal problems and dilemmas in EU health law, and apply this knowledge on similar issues
- The student will be able to formulate relevant legal arguments in the EU health legal debate,
- Encouraging students to develop competence in communication skills,
- The student will be able to analyse and summarize the case law of the EU Court of Justice on health integration issues,
- The student will be able to apply the acquired knowledge in writing an academic legal paper on European integration and health law,
- Promoting innovation in teaching. The innovative teaching method (mix of various teaching methods, student-centred approach and combination of enhancing knowledge and skills) combined with applied (digital) tools stimulate a more problem-solving learning process, therefore fostering new teaching methods and technologies which contributes to enhance communication skills and further understanding of this part of European integration.
- In addition, the open access digital technologies enable other participants worldwide to increase their knowledge and understanding of European integration of health law issues, and receiving periodical feedback via social media.

2.2 Contact

Course lecturer and coordinator: André den Exter, room J6-05 (Bayle building, EUR, denexter@law.eur.nl)

2.3 Participation requirements

Students are expected to attend **all** classes (with notification for an excused absence) and to actively engage in discussion and group work.

Preparation for classes

The course will involve weekly readings (hereafter). Students are required to come to class prepared to discuss the day's readings. These readings will be available online at the course page.

Optional readings are provided for those who want to engage further with particular topics.

Early March 2019, and based on class interest, an optional field visit to European Parliament (Brussel) will be organised.

2.4 Mandatory and suggested literature

Mandatory literature

T. Hervey and J. McHale, EU Health Law. Themes and Implications, CUP 2015 (Library copy available)

Curia website: EUCJ rulings, source: <http://curia.europa.eu>

2.5 Schedule

| | |
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| Week | 9 |
| Type of meeting | Lecture, seminar: Introduction EU law, Human Rights and Health, EU law and Public health, Global Health |
| Lecturer | André den Exter |
| Details Subjects: This session focuses on EU law, providing a general introduction of understanding the EU substantive law on European integration and health, EU Human Rights Charter and Health, and explaining the role of the EU in public health issues. Topics: Course outline, General introduction EU law and policy, European integration and health care, human rights in healthcare, role of the CJEU; internal and external policies webinar mini lecture EU public health law; (concepts; action programmes and principles; seminar on protecting people from (cross border) health threats and promoting good health (case communicable diseases and early warning systems. | |

Aim: explaining the concept of EU public health law, regulatory instruments (hard law and soft law)
 Students will be confronted with real life public health threats, focussing on its regulatory consequences and discussing legal/policy options at EU/national level.
 Case studies: tbc
 Case law: case C-547/14, *Philip Morris Brands and Others* (Philip Morris)

Mandatory literature

T. Hervey and J. McHale, EU Health Law. Themes and Implications, CUP 2015, ch. 3,
 Case C-362/14, Maximilian Schrems v Data Protection Commissioner, source:
<http://curia.europa.eu>
 T. Hervey and J. McHale, EU Health Law. Themes and Implications, CUP 2015, chs. 15 & 18

Case law

- Case C-34/10 *Oliver Brüstle v. Greenpeace e.V.* [2011] oJ c 362/5 Judgment of the Court (Grand Chamber) of 18th of October 2011. (source: <http://curia.europa.eu>)
 The case is a reference for a preliminary ruling under Article 267 TFEU from the German Bundesgerichtshof made decision 17 December 2009 on the interpretation and scope of application of Article 6.2.c of Directive 98/44/EC

Recommended literature (for further study)

Frischhut, M. (2013). (summary) Fundamentals of European Union law: (3rd edition).
 Wien: Linde), chs. 3-6
 Tuomas Ojanen, Making the Essence of Fundamental Rights Real: The Court of Justice of the European Union Clarifies the Structure of Fundamental Rights under the Charter ECJ 6 October 2015,
 European Constitutional Law Review, 12: 318–329, 2016, doi:10.1017/S1574019616000225
<https://www.cambridge.org/core/services/aop-cambridge-core/content/view/C31AEE0EBF7843019DC088DE1712100B/S1574019616000225a.pdf/div-class-title-making-the-essence-of-fundamental-rights-real-the-court-of-justice-of-the-european-union-clarifies-the-structure-of-fundamental-rights-under-the-charter-div.pdf> European Constitutional Law Review, 12: 318–329, 2016, doi:10.1017/S1574019616000225
 A den Exter, Policy. Embryonic stem cell patents at European top court, European Journal of Human Genetics (2015) 00, 1. doi:10.1038/ejhg.2015.98
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4755387/>
 Rik de Ruiter, Full disclosure? The Open Method of Coordination, parliamentary debates, European Union Politics 2013 14: 95, DOI: 10.1177/1465116512458836
 S. Greer et al, The hard politics of soft law: the case of health, ch. 4 in T Hervey et al, Health care and the EU: the law and policy patchwork, in E. Mossialos et al, Health Systems Governance in Europe. CUP 2010
 Elisabet Ruiz Cairó. Insight, Different Arguments Lead to the Same Result: The Tobacco Products Directive Is Declared Valid by the Court of Justice, European Papers, Vol. 1, 2016, No 2, pp. 741-749 doi: 10.15166/2499-8249/66 (European Forum, 20 August 2016)
http://www.europeanpapers.eu/en/system/files/pdf_version/EP_EF_2016_I_037_Elisabet_Ruiz_Cairo_0.pdf
 T Hervey et al, Health care and the EU: the law and policy patchwork, in E. Mossialos et al, Health Systems Governance in Europe. CUP 2010
 Louise Van Schaik, The EU's Performance in the World Health Organization: Internal Cramps after the 'Lisbon cure' Journal of European Integration, Vol. 33, No. 6, 699–713, November 2011 <http://dx.doi.org/10.1080/07036337.2011.606692>
 DECISION No 1082/2013/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC

Council of the European Union Brussels, 7 December 2015 Council conclusions Council conclusions 'Lessons learned for Public Health from the Ebola outbreak in West Africa'

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| Week | 10 |
| Type of meeting | Mini lecture, seminar: Patient Mobility |
| Lecturer | André den Exter |
| Details Webinar mini lecture mobility of patients; seminar on patient mobility in the EU (case studies); 'Is Eurostar the Answer?' Aim: Explaining the concept of EU patient mobility, history, presence, and future Scheduled feedback moment 1 for Online participants (1 hour) Case study: Leger case | |
| Mandatory literature A den Exter (ed.) Cross-border health care and European Union law (eBook: https://www.academia.edu/34975307/Patient_Mobility_and_EU_law) Case law: Smits/peerbooms C-157/99; Petru, C-268/13; Watts C-372/04; Elchinov C-173/09 | |
| Recommended literature (for further study) Vassilis Hatzopoulos and Tamara Hervey, Coming into line: the EU's Court softens on cross-border health care Health Economics, Policy and Law, Volume 8, Issue 1 January 2013, pp. 1-5 https://www.cambridge.org/core/services/aop-cambridge-core/content/view/3C9DE8BBC9F21910E715B126728AC7B2/S1744133112000102a.pdf/div-class-title-coming-into-line-the-euandapos-s-court-softens-on-cross-border-health-care-div.pdf M Frischhut, N Fahy, Patient mobility in times of austerity. A legal and policy analysis of Petru case, EJHL 2016 (36-60) http://booksandjournals.brillonline.com/content/journals/10.1163/15718093-12341378 Commission report on the operation of Directive 2011/24/EU on the application of patients rights in cross-border healthcare, 2015 http://ec.europa.eu/health/sites/health/files/cross_border_care/docs/2015_operation_report_dir201124eu_en.pdf Wolf Sauter, Harmonisation in healthcare: the EU patients' rights Directive 2012 European Commission, report from the Commission on the operation of Directive 2011/24/EU, COM (2018) 651 final, Brussels 21.9.2018 | |

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| Week | 11 |
| Type of meeting | Mini lecture, seminar: Professional mobility |
| Lecturer | André den Exter |
| Details Health Professionals webinar mini lecture mobility of health professionals (mutual recognition diplomas); seminar on professional mobility legislation and ECJ rulings; case 'Problem doctors' Aim: explaining and discussing legal consequences of professional mobility in the EU. Case study: professional mobility in the EU Scheduled feedback moment 2 for Online participants (1 hour) | |
| Mandatory literature T. Hervey and J. McHale, EU Health Law. Themes and Implications, CUP 2015, chs. 6 | |

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| <p>M. Peeters, The Relevance of Directive 2005/36 on the recognition of professional qualifications, in: Cross-border health care and EU law (A. den Exter: https://www.academia.edu/34975307/Patient_Mobility_and_EU_law)</p> <p>Greece to end discrimination on nurses qualifications http://europa.eu/rapid/press-release_IP-10-1556_en.htm</p> | |
| <p>Recommended literature (for further study)</p> <p>Thomas Gerlinger Transnational migration of health professionals in the European Union, Cad. Saúde Pública, Rio de Janeiro, 23 Sup 2:S184-S192, 2007</p> | |
| <p>Week</p> <p>Type of meeting</p> <p>Lecturer</p> | <p>12</p> <p>Data Protection Mini lecture & seminar, guest lecture</p> <p>Andre den Exter</p> |
| <p>Details</p> <p>webinar mini lecture EU data protection law</p> <p>seminar: case study Estonia Genetic Biobank and DP</p> <p>aim: explaining and discussing legal consequences of the GDPR to health care</p> | |
| <p>Mandatory literature</p> <p>P. Voigt, The EU GDPR. A Practical Guide, Springer verlag 2017 (ebook via Erasmus University library)</p> <p>V. Chico, the impact of the GDPR on health research, British Medical Bulletin, 2018, 128:109–118</p> <p>J Herveg, Data protection and Databanks 2018, p 479-500</p> <p>S Slokenberga, Biobanking between the EU and 3rd countries – can data sharing be facilitated via self regulatory tools? EJHL 2018, p 517-538</p> <p>M. Mostert et al, From privacy to data protection in the EU: Implications for big data health research, EJHL 25 (2018), p 43-55 (EUR library)</p> <p>M Shabani, P Borry, rules for processing genetic data for research purposes in view of the new EU GDPR, European Journal of Human Genetics (2018) 26:149–156</p> <p>https://doi.org/10.1038/s41431-017-0045-7 (EUR library)</p> <p>D Townsend, Conclusion: harmonisation in genomic and health data sharing for research: an impossible dream?, Human Genetics (2018) 137:657–664</p> | |
| <p>Recommended literature (for further study)</p> <p>Handbook GDPR 2018ed., EU Agency for Fundamental Rights, chs 4 & 6</p> | |
| <p>Week</p> <p>Type of meeting</p> <p>Lecturer</p> | <p>13</p> <p>Mini lecture, seminar: Pharmaceuticals</p> <p>André den Exter</p> |
| <p>Details</p> <p>webinar mini lecture EU pharmaceutical law (clinical trials, market authorization; borderline medical products, pharmacovigilance, internet sales medical products)</p> <p>seminar 1: information and advertising v. inducement; seminar 2. Clinical trials tragedy: the Seroxat case;</p> <p>Cases:</p> <ol style="list-style-type: none"> 1. Outsourcing clinical trials in Burundi; 2. Counterfeiting life-saving medicines in a global world: the role of the EU’; | |

Aim: explaining and discussing the role of the EU in regulating CTs, fighting counterfeit medicine, the clash between IPs and Access to Medicines

Seminar: cases studies discussion

Scheduled **feedback moment 3** for Online participants (1 hour)

Mandatory literature

T. Hervey and J. McHale, EU Health Law. Themes and Implications, CUP 2015, chs. 12, 13

Recommended literature (for further study)

Annagrazia Altavilla Ethical Standards For Clinical Trials Conducted In Third Countries: The New Strategy of the European Medicines Agency European Journal of Health Law 18 (2011) 65-75

A Mahalathchimy, et al, The European Medicines Agency, 31 Med Law 2012, 25-42

Open Clinical Trial Data for All? A View from Regulators

Hans-Georg Eichler, Eric Abadie, Alasdair Breckenridge, Hubert Leufkens, Guido Rasi, PLoS Medicine | www.plosmedicine.org 1 April 2012 | Volume 9 | Issue 4 | e1001202

Mareen Poser DTCA of Prescription Medicines in the European Union: Is There Still a Need for a Ban? European Journal of Health Law 17 (2010) 471-484

Nicolas de Sadeleer, Restrictions of the Sale of Pharmaceuticals and Medical Devices such as Contact Lenses over the Internet and the Free Movement of Goods, European Journal of Health Law 19 (2012) 3-28

Eugenie Syx, The Case of the Electronic Cigarette in the EU, European Journal of health law 21 (2014) 161-175

Andrea Faeh, Giving Information on Medicinal Products to the General Public — In Search of a Definition to Safeguard the Patient, European Journal of health law 21 (2014) 176-195

A. Mahalatchimy Access to Advanced Therapy Medicinal Products in the EU: Where Do We Stand? European Journal of Health Law 18 (2011) 305-317

Editorial, Drug Companies Should Be Held More Accountable for Their Human Rights Responsibilities, The PLoS Medicine Editors, September 2010 | Volume 7 | Issue 9 | e1000344

The PLoS Medicine Debate Are Drug Companies Living Up to Their Human Rights Responsibilities? The Perspective of the Former United Nations Special Rapporteur (2002-2008)

Anand Grover, Brian Citro, Mihir Mankad, and Fiona Lander Pharmaceutical Companies and Global Lack of Access to Medicines: Strengthening Accountability under the Right to Health 234 journal of law, medicine & ethics

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| Date: tbc | Field visit EU Parliament (to be confirmed)(min. 12 participants) |
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| Week | 14 |
| Type of meeting | EU Competition law and Healthcare Mini lecture & seminar, |
| Lecturer | guest lecture Andre den Exter |
| Details | |

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| <p>Webinar mini lecture EU competition law; Seminar: case study the 'Pharmaceutical sector Inquiry: Johnson&Johnson and payed-for delay tactics'</p> <p>Aim: explaining and discussing the role of EU competition law in health care</p> <p>Scheduled feedback moment 3 for Online participants (1 hour)</p> |
| <p>Mandatory literature</p> <p>T. Hervey and J. McHale, EU Health Law. Themes and Implications, CUP 2015, chs. 9, 11</p> <p>W. Sauter, the impact of European competition law on national health care systems, European Law Review, (2012) https://pure.uvt.nl/ws/files/1457810/2012_032.pdf</p> |
| <p>Recommended literature (for further study)</p> <p>T Prosser, EU Competition law and public services, in: T Hervey et al, Health care and the EU: the law and policy patchwork, in E. Mossialos et al, Health Systems Governance in Europe. CUP 2010</p> <p>V. Hatzopoulos, Public procurement and state aid in national health care systems, in: J VAN DE GRONDEN, the Treaty Provision on Competition and Health Care, ch 11</p> |

2.6 Exam and resit

There will be no exam. Instead, students will write an individual paper (in English)

Students are requested to write an individual paper (5,000 words excluding references) that will be graded.

How to Write a Paper?

The Paper as a Method of Assessment

Rationale: The writing of a paper is intended to test your ability to:

- (a) demonstrate knowledge, understanding and critical evaluation of relevant legal documents, cases and publications;
- (b) to communicate information and ideas in writing, sustained by evidence and other supporting data;
- (c) to complete a piece of written work in a given time.

Choice of Topic

Unless the supervisor has assigned a specific topic on which you should write your paper you will be free to write on a topic of your choice. It is wise to choose a topic that interests you. Do not attempt to write on something on which there is very little

available literature or documentation. You should try and define the purpose and scope of your paper as soon as possible and, wherever necessary, in consultation with your supervisor.

Planning the Paper

As soon as (a) you have been assigned a specific topic, or (b) you have agreed the topic of your paper with the supervisor, try to allocate some time to thinking and planning the paper. Try also to identify the specific problem that you intend to research by formulating an overall question (in case the topic assigned to you is not already formulated in question form), or thesis, for your paper. Allow yourself plenty of time (a) to search for information in paper-based resources, for example books, periodicals, reports, conference proceedings, etc. and in electronic resources, for example on the Internet, (b) to collect and analyse data, (c) to write your paper and to revise it. Make use of publications that are available in the Erasmus University library, searching through the database on <http://cat.ubib.eur.nl:8080/DB=1/LNG=EN/> to include introductory textbooks, advanced treatises, monographs and current legal periodicals. Of course you may use of publications that are available in other libraries, such as the Peace Palace Library (www.ppl.nl).

You should draw up a topic outline for the whole paper, divided into sections, with relevant headings and sub-headings (see further in this paragraph). A good way to do this is to begin with a first draft of the Introduction, treating this section as the terms of reference for the rest of your paper (see the next section, for details of what the Introduction should contain). Once you have completed this introductory section you will be able to allocate 'working' headings and sub-headings to your paper, drawn from the points that you have already noted in the introduction.

Structure of the Paper

Your paper should be divided into numbered sections and, if necessary, subsections that represent the headings and sub-headings in the paper. Titles of sections should be written either (1) in bold-type or (2) underlined or (3) in italics, to distinguish them from the rest of the text.

Introduction: The introduction is intended to briefly inform the reader about the topic of the paper. It should contain a definition, or formulation, of the problem that you intend to investigate, together with a number of sub-categories in which you add further statements, or raise questions, that you will address during the course of your paper. You should explain your reasons for writing on the subject and describe how the paper is organised. Remember that the introduction should lead the reader into the substantive part of the paper.

Main Part: The introduction should be followed by one or more substantive sections and/or subsections, under each separate headings and/or sub-headings. It is advisable to group each of your arguments into a section and secondary points of those arguments into sub-sections. This part must contain an extended discussion of the topic, highlighting issues and any problems that arise in those issues (where

available you should also give the solutions, or refer to developments, that address the issues/problems). Try and analyse the main points of each of your arguments and seek to present them in a clear, concise and logical fashion. You must be able to sustain your argument(s) with evidence or supporting data, i.e. the primary and secondary sources which you have researched and read. Reference to these sources should be reserved for footnotes, more about which below. Remember to be critical in searching for inconsistencies and redundancies in your argument(s).

Avoid long, involved sentences. Try not to present your argument in an extreme form, either by saying very little about a very large subject or saying a lot about a very detailed subject – you will either confuse or bore the reader. Seek to build your argument(s) and remember to check whether you have answered the research questions that you may have set yourself in the Introduction, or elsewhere in the text. Do not forget to tie together points made in your argument(s) that lead the reader to your findings and/or conclusion.

Conclusion: You should close your paper with a “Conclusion” or “Conclusions” (in some instances this might be expanded to “Summary and Conclusions” where several different arguments have been analysed – it will also help to focus the reader on your conclusion(s)). Avoid any repetition of the argument(s) that you have made in the main part of your paper.

Reference to Sources

You must give full credit to the primary and secondary sources of outside information that you have come across during your research and upon which you have drawn in order to write your paper. In addition to direct quotations, footnotes must be used whenever you summarise, or paraphrase an author. If you do not give full credit to your sources upon which your ideas are drawn, and which may form part of your argument, then you are guilty of plagiarism.

NB. Plagiarism is the act of appropriating the composition (or text) of another, or parts, or passages of those writings, or the ideas, or language of the same, and passing them off as the product of your own mind. This is a serious violation and, in the event that you are caught in the act of plagiarism, you will be dealt with accordingly.

Please, check the university plagiarism policy at:

http://www.eur.nl/eur/corporate_publicaties/fraude_en_plagiaat/

Try to show that the writing in your paper is a product of your thoughts and ideas on the subject, with correct citation to your primary and secondary sources whenever you have used such sources. You may copy phrases, sentences, or small sections of text from a book, journal or internet web-site, and add it to the text of your paper, which contains your own language, in order to support or illustrate an argument that you wish to make. Only cite what is necessary and be aware that it is often more effective to put a proposition, or an argument that you have read about into your own words.

When you wish to cite a phrase, whole sentence, or small section of text from a book, journal, or internet web-site, that you have consulted, you must (a) be careful

to copy the phrase, sentence, or piece of text accurately, (b) be careful to place quotation marks (“...”) around the text, and (c) give a full citation to the source from which you took the text, in a footnote, or endnote, to the paper.

Tips for Reporting Sources

The following tips are intended to assist you with particular aspects of reporting your sources:

Citations

Note that the Oxford Standard for Citation of Legal Authorities

Check guidelines and criteria for writing a legal paper:
(<http://denning.law.ox.ac.uk/published/oscola.shtml>) is obligatory.

Footnotes only! You should use footnotes to convey the information that you wish to provide concerning the reference sources that you have used as a basis for, and in preparation of, your paper.

Cover Sheet/Title Page

Provide a cover sheet that gives the title of your paper, preferably in the middle of the page. Add (1) your name (2) your student number (3) the title of the course for which the paper is intended (4) the title of your lecturer/supervisor, (5) the date, and (6) the number of words in the paper.

Table of Contents

The next page should include a table of contents that (1) lists the headings and (2) relates those headings to page numbers. A table of contents makes it easier for the reader to see at a glance how you have organised your paper and what line of reasoning you intend to develop.

ASSESSMENT

Ensure your work is written in correct English **before** submission.

By writing an individual paper, the student will be able to apply the acquired knowledge on European integration and health law.

Grade: the individual paper will decide the final grade (100%). The paper has to be passed successfully.

Resit

In case of re-submission, you have to select a new paper topic. The conditions for re-submission are similar as during the previous paper.

Important dates and reviews

Papers should be submitted by using the 'upload box' in Canvas. Paper submission **deadline: 19 April 2019 (deadline 10 am), resit paper submission: 1 June 2019 (10 am).**

Before writing your paper you should find out exactly what is required of you and how the paper will be assessed. Make sure that you can complete the task of researching and writing the paper in the time available, without neglecting your other subjects or interfering with your preparation for examinations. It is important to pace yourself!

How You'll Be Graded?

You'll be graded on three basic criteria:

1. How well do you understand the issues you're writing about?
2. How good are the arguments you offer?
3. Is your writing clear and well-organized?

We do not judge your paper by whether we agree with its conclusion. In fact, we may not agree amongst ourselves about what the correct conclusion is. But we will have no trouble agreeing about whether you do a good job arguing for your conclusion.

More specifically, we'll be asking questions like these:

- o Do you clearly state what you're trying to accomplish in your paper? Is it obvious to the reader what your main thesis is?
- o Do you offer supporting arguments for the claims you make? Is it obvious to the reader what these arguments are?
- o Is the structure of your paper clear? For instance, is it clear what parts of your paper are expository, and what parts are your own positive contribution?
- o Is your prose simple, easy to read, and easy to understand?
- o Do you illustrate your claims with good examples? Do you explain your central notions? Do you say exactly what you mean?
- o Do you present other lawyers' views accurately and charitably?

General outline assessment

| criteria | assessment | explanation |
|---------------------|--------------------|-------------|
| | U; p; s; ms; g; vg | |
| Research question | | |
| Content and sources | | |
| Internal structure | | |
| Argumentation | | |
| Applying theory | | |

| | | |
|---|--|--|
| Style and layout | | |
| Dedication/independence | | |
| | | |
| | | |
| Final assessment and mark | | |
| U: unsatisfactory; p: poor; s: satisfactory; ms: more than satisfactory; g: good; vg: very good | | |

3. Course activities

3.1 (Guest) lectures

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3.2 Workgroups

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3.3 Individual (upload) assignments

n/a

3.4 Group assignments

n/a...

3.5 Plagiarism

EUR rules for plagiarism are applicable