Guidance for evaluating exams – HLAW4100 – fall 2018

The topics included in the assignment have been covered in lectures, syllabus and rehearsals. The course focuses on the impact of international law on the regulation of public health systems. Therefore, it starts by identifying the system for global regulation of health law and policies, including underlying principles of international law, as well as global and regional health governance institutions and actors (World Trade Organization (WTO), World Health Organization (WHO), the European Union (EU) and non-governmental organizations (NGOs)/civil society). The course addresses issues such as access to medicines, people's rights to health care, market competition in health care, regulation of health professionals' qualifications, and regulation of pharmaceuticals. These issues are all influenced by legal standards as defined by international law. At the end of the course students should have an overview of the system for global (and EU) health governance, central international health rules and institutions (WTO, WHO, EU), and an understanding of the interface between international law/EU law and national health law and policies. Thus, the students are expected to recognize and describe different regulatory regimes in the health care field (WTO, UN/WHO, EU) and understand how these organizations/regimes affect nation states. This should be taken into consideration when evaluating the exams.

It is important to stress that the students are not expected to cover all the elements included in this evaluation guide. However, they are expected to cover the basic principles, structures and functions of the regulatory regimes referred to above, to see and discuss links between them, and to be able to discuss the possible impact for health regulation.

The exam consists of two main questions: 1) one essay and 2) five questions of which the students answer three. The candidates are required to answer both question 1 and 2. Question 1 counts 50 %, and Question 2 counts 50 % in the grading of the whole exam. Under question 1 the candidates must answer EITHER essay A OR essay B. Under question 2 the candidates must answer three out of five sub-questions. The sub-questions under Question 2 have equal weight in the grading. The grades should be set according to established norms for setting grades as practiced at the University of Oslo (see Appendix 1).

Question 1

A: *Give a short description of the core institutions of the European Union (EU) and the core principles of the EU's internal market, including the principles of free movement. Give a short historic account of how the EU gradually has become more involved in health law since the signing of the Rome treaty in 1957 up until present day. Finally discuss how the regulation of the internal market and the principles of free movement have spilled-over to the health sector and triggered the development of new EU health laws. Provide concrete examples.* Use the title: ***EU, free movement and health***

This topic is well covered by syllabus, lectures, as well as rehearsals. The students should be able to identify and describe the core functions of the following institutions:

- ***European Council***: Heads of states and governments – headed by its own President – general political direction and priorities
- ***Council of the European Union***: Government representatives – 'Council of ministers', legislative body

- ***European Parliament***: Directly elected representatives since 1979 – legislative body
- ***European Commission***: Initiator/agenda-setter – administrative/executive branch, information-gathering, supervision and control, implementation and enforcement
- ***European Court of Justice***: interprets EU law to make sure it is applied in the same way in all EU countries, settles legal disputes related to infringement of EU law by a Member State

The students should moreover be able to identity, the core principles of the EU's internal market, including the principles of free movement: free movement of persons, goods, capital and services. The students should be able to identify the internal market as a core part of the (economic) integration process between the EU member states and as a way of guaranteeing the free movements (of goods, capital, services, and labour/persons). The market encompasses the EU's 28 member states (soon 27, c.f. Brexit). Extra points to those who mention that the internal market, with some exceptions, is extended to Norway, Iceland and Liechtenstein through the EEA Agreement, and to Switzerland (with some exceptions) through bilateral agreements. Also extra points to those who relate the internal market to the core goal of the EU of progressive integration of Member States' economic and political systems. The students should be able to identify three major areas of EU influence on health law:

- Shaping the context of health systems (through hard law, soft law, case law) (e.g. internal market rules)
- Directly addressing public health issues, such as obesity, alcohol, smoking and food safety
- EU and global health – major actor in trade, but also WHO, FAO, OIE etc. – shapes and is shaped by global rules

As to the historical account of the development of EU health law, the students should go back to the Treaty of Rome of 1957, which lay down the foundations for the coordination of social security among the member states through the principles of free movements and through the provisions on social policy. The principles of free movement, which implies that the EU "prohibit practices that prevent or distort free competition, and to promote free movement of goods, persons, services and capital". The students should be able to show how these principles have affected the later development of EU health law (regarding authorization of medicines, mutual recognition of qualifications for health personnel, common health (product) standards, standards for medical devices, social security coordination, cross-border care/patient mobility etc.). In addition to the Treaty of Rome, the students should refer to the work following the Single European Act of 1987 of removing remaining trade barriers and thereby achieving the goal of establishing a well-functioning single European market. This work included a strengthening of the emphasis on the health aspects of market integration (c.f. Article 100A of SEA: "3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection"). The intensified work on the single European market project thus triggered the development of common health rules and policies in the EU, eventually also a separate Treaty based "health paragraph" (c.f. Lisbon Treaty's Article 168: *Public Health* (ex. Art. 129 and ex. Art. 1562). In the 1990s and 2000s, the EU thus extended its involvement in health policy and law. The EU adopted new common health rules and also established a separate health administration at the EU level, illustrated by DG Sante, as well as a number of EU agencies working on health issues (such as European Medicine Agency,

European Food Safety Authority, and European Centre for Disease Prevention and Control). The students should be able to provide examples from this process, such as regulation of medicines, Social Security Coordination mechanism, Patients' Rights Directive and food safety regulation. They should also be able to separate between hard law (binding) and soft law (non-binding) and to describe how the EU is involved in both. Extra points for those who refer to the EU Charter of fundamental Rights, 2000, where Art 35. Health care states: "Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities." The Charter became legally binding through the Lisbon Treaty (2009). In the discussion, the students should demonstrate that they understand the principles of free movement, and how these freedoms are linked to the development of health law within the EU. Examples: *free movement of goods* (food safety, medicines, medical devices etc.), *free movement of services* (cross-border care, health services), *free movement of people* (labour rights/social security rights, patient mobility, mutual recognition of qualifications) etc. They should also demonstrate an understanding of "spill-over effects", i.e. that health law and policy have been affected by EU's internal market regulation even though health was not the original target of this regulation. It is relevant to refer to the concepts of "uninvited Europeanization" or "unintended Europeanization" in this context. Extra points to those who demonstrate an understanding of EU law and the proportionality principle. The proportionality principle can be viewed as a general legal principle and a logical method intended to strike the correct balance between a restriction imposed by a corrective measure and the severity of the nature of the prohibited act. In the health area, it can justify state intervention to protect national health systems based on exceptions from internal market rules because of health as a general interest and legitimate concern. As to EU law, the students should be able to separate between primary law (Treaties – every action taken by the EU is founded on treaties), and secondary law (*regulations* – as soon as passed, binding legal force in Member Stated, on a par with national laws, *directives* – addressed to national authorities, who must then take action to make them part of national law, and *decisions* – apply in specific cases, particular countries etc.). They should also demonstrate an understanding of EU Case law, which is made up of judgments from the European Union's Court of Justice, which interpret EU legislation. This last point is particularly relevant in the case of cross-border care, where Court ruling lay down the foundation for developing the Patients' Rights Directive. It is important that the students show that they understand that the principles of free movement are Treaty based (and thus primary law) and thus, that other laws (such as health laws) must comply with these principles.

B. *What are the core objectives of the World Trade Organization (WTO) and the World Health Organization (WHO)? Describe the possible relevance of the WTO and the WHO respectively, for tobacco control. Refer to specific agreements/disputes. Describe some possible dilemmas of linking trade law and health law. Finally, discuss some of the key challenges of enforcing global/international health law in general and enforcing the "right to health" in particular. Use the title:* ***International law, tobacco control, and right to health***

The core function of the WTO is to provide a framework for the regulation of world trade. The following points are relevant here (c.f. Preamble of WTO Agreement): By (i) reduction of tariffs and other trade barriers and (ii) elimination of discriminatory treatment, to facilitate:

- expansion of production of, and trade in, goods and services; and increase of standards of living

- attainment of full employment
- growth of real income and effective demand
- provide the common institutional framework for the conduct of trade relations among its Members (….)
- framework for new negotiations

Key logic is to achieve welfare gains through trade liberalization, non-discrimination, and the regulation of trade measures.

The core function (and objective) of the WHO is to be the "directing and coordinating authority on international health within the United Nations' system". This is sought achieved by providing leadership on matters critical to health and engaging in partnerships where joint action is needed:

- shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge;
- setting norms and standards and promoting and monitoring their implementation;
- articulating ethical and evidence-based policy options;
- providing technical support, catalyzing change, and building sustainable institutional capacity;
- monitoring the health situation and assessing health trends

As for Tobacco Control, it is important to separate between tobacco as "trading goods" (where the WTO is particularly relevant) and tobacco as a "health threat" (where the WHO is particularly relevant). Thus, tobacco is relevant under different international regulatory regimes depending on the context.

Tobacco can be relevant under different WTO agreements, but here it is expected that the students refer to the TRIPS Agreement and the TBT Agreement, as these two agreements were involved in the Tobacco dispute between Australia and tobacco-producing countries, which is mentioned in the syllabus and which have been widely discussed in lectures and rehearsals/student presentations. The students should be able to describe the core functions of these two agreements and how they relate to tobacco control (TRIPS: trade-related intellectual property rights such as trademarks/patents/geographical indicators; TBT: technical barriers to trade such as packaging and labelling).

As to the WHO and tobacco control, the students must refer to the WHO's Framework Convention on Tobacco Control (FCTC) of 2003. The core demand reduction provisions in the WHO FCTC are contained in articles 6-14:

- Price and tax measures to reduce the demand for tobacco, and
- Non-price measures to reduce the demand for tobacco, namely:
- Protection from exposure to tobacco smoke;
- Regulation of the contents of tobacco products;

- Regulation of tobacco product disclosures;
- Packaging and labelling of tobacco products;
- Education, communication, training and public awareness;
- Tobacco advertising, promotion and sponsorship; and,
- Demand reduction measures concerning tobacco dependence and cessation.

The core supply reduction provisions in the WHO FCTC are contained in articles 15-17:

- Illicit trade in tobacco products;
- Sales to and by minors; and,
- Provision of support for economically viable alternative activities.

The students are not expected to describe and discuss all these elements, but must demonstrate a basic understanding of how WHO regulates tobacco control through the FCTC as a hard-law instrument. They should also refer to the problems of enforcing this agreement, because among other things, of the lack of effective enforcement mechanisms and the openness and flexibility of the wording of provisions of the agreement.

The students should also be able to refer to the basics of the so-called "WTO Tobacco Case" (2014) between Australia on one side and Honduras, Indonesia, Dominican Republic and Cuba on the other. The background for this WTO dispute was Australia's adoption of the Tobacco Plain Packaging Act – TPPA – in 2011, which imposed trademark restrictions and other plain packaging requirements on tobacco products. TPPA had triggered Phillip Morris to file two cases against Australia: 1) A case, which went to the Australian High Court and 2) The case of Hong Kong-Phillip Morris vs. Australia related to a Bilateral Investment Treaty. Phillip Morris did not win through in any of these cases, but decided to support tobacco-producing countries in legal proceedings under the WTO. It is important in this context that the students understand that the WTO is a member-state driven organization, which means that only member states can file cases and initiate disputes under the WTO's legal framework. Australia's justification for restrictions on Tobacco where, among other things, to improve public health and discourage smoking/encourage cessation. Australia also justified the restrictions by referring to the provisions and recommendations included in the WHO – Framework Convention on Tobacco Control. Some of the main claims by complainants where that the restrictions represented breaches of the TRIPS Agreement (trademarks, geographical indications) and the TBT Agreement (labelling, product standards), that the restrictions were unnecessary barriers to trade, discriminatory and, that they were detrimental to other countries' tobacco industry (e.g. Cuba: premium Cuban cigars can no longer be differentiated from other products). Some of the main conclusions of the WTO Panel report, which was published 28 June 2018, were:

- Australia were allowed to retain its restrictive Tobacco laws and regulations
- The complaining countries lost on all major points
- WHO's Framework Convention on Tobacco Control important as part of the scientific evidence in support of Australia's measures

The dispute highlights the link between trade (WTO) and public health (WHO – Framework Convention on Tobacco Control). The WHO praised the ruling and said it would most likely

"accelerate" the rollout of similar packaging in other countries. In fact, the dispute has triggered changes in tobacco laws in even more countries (such as Norway).

The students are not expected to discuss all the details of this dispute, but should be able to refer to the basics. Moreover, the dispute is relevant for discussing the dilemmas of linking trade law and health law. It is expected that the students can refer to the dilemma of using trade liberalization as a way of achieving welfare gains, weighed up against the right of each country to set their own levels of (health) risks and to decide how to deal with these risks (c.f. for example Australia's plain packing rules). As to the challenges of enforcing global/international health law/the "right to health", several elements are relevant, such as the issue of state sovereignty and health sovereignty, differences in capacity, knowledge and wealth between states, developed vs. developing countries, different interests, rise of non-governmental actors, which are hard to govern, funding (included funding earmarked by donors), differences in how the "right to health" is interpreted, and the issue of dispute settlement/enforcement mechanisms. In lectures, the following points have been particularly highlighted:

- Treaty compliance
- Accountability mechanisms – Who is responsible and how to make them responsible?
- No coercive sanctions in case of violations
- International human rights courts not well equipped to deal with economic and social rights
- Availability of national courts? It's up to national courts whether to accept cases…

The students are as a minimum expected to discuss the problems of Treaty compliance/dispute settlement/enforcement/sanctions and are expected to compare the WTO and the WHO with regard to these elements. The best students will bring other elements (as those mentioned above) into the discussion.

Question 2:

Answer three of the following questions:

a) Describe shortly the basic elements of the WTOs TRIPS (Trade-related Intellectual Property Rights). Provide a short discussion of the possible implications of this agreement for the health sector/health law.

The background for the negotiation of the TRIPS agreement during the GATT Uruguay Round of negotiations and the subsequent establishment of TRIPS as one of the agreements under the World Trade Organisation ((WTO) in 1995, was the view that there was a need to establish binding international rules to protect Intellectual Property Rights (IPRs). Failure to protect IPRs, were by several states (among them the United States) considered as unfair trade practises and thus relevant for the WTO. IPRs refer to rights to ownership of intellectual work, i.e. legal rights a person or company has to ideas, designs, and inventions, including copyrights, patents and trademarks. Thus IPRs are basically about distribution of rights, influence and "power" between market actors (e.g. pharmaceutical industry), within and across borders. A core element of TRIPS, which is relevant for the health sector, is patent protection, i.e. time-limited monopolies to owners of a patent. The reason for providing such rights is, among other things, to ensure innovation/new technologies/develop new medicines.

The problem is that such protection creates market domination and may contribute to push prices up. Another problem is that IPRs have limited impact on research incentives in developing countries = raise prices and thus transfer rents to patent-holders in developed countries. Thus, there is an on going controversy related to prices charged by pharmaceutical companies for patented medications. The critique is that TRIPS regulates/gives IPR protection to pharmaceutical manufacturers of which the biggest ones are in developed countries Developing countries thus seek to reduce prices with measures that pharmaceutical industry say infringe on their IPR/TRIPS rights. Subsequently, developing countries risk ending up in WTO disputes. One important question is how to deal legally with the problem of price/availability of medicines? Art. 27 of the TRIPS Agreement says that governments can refuse to grant patents for 3 reasons related to public health: 1) inventions whose commercial exploitation needs to be prevented to protect human, animal or plant life or health — Article 27.2; 2) diagnostic, therapeutic and surgical methods for treating humans or animals — Article 27.3a; 3) certain plant and animal inventions — Article 27.3b.

Other ways to go around IPR/patent protection are:

- "Piracy" – illegal copies (c.f. also "counterfeiting products") – producing and marketing a patented product without permission from patent-holder (considered illegitimate in many (developed) countries).
- Parallel imports (from countries with lower prices) – products marketed with the patent owner's permission in one country and imported into another country without approval of patent owner (not regulated by TRIPS)
- Compulsory licenses – to use the subject matter of a patent without authorization of a Right holder (c.f. TRIPS, Article 31) – first, negotiating voluntary license – if fails: compulsory license an option; national emergency, reserved for supply of domestic market, time-limited licenses. Right-holders must still receive compensation.

Some of the problems of regulating/not regulating IPRs are:

- Reduced rent = reduced price-discrimination = unwillingness to sell at low prices where demand is weak = developing countries priced out of markets
- Countries with weak production capability may have difficulties in exploiting compulsory licensing (partly dealt with through the amendment of the TRIPS Agreement)
- Research incentives in pharmaceutical sector may drop

The threat to use compulsory licensing and parallel imports may in itself keep prices down. Main focus in the course has been on the relevance of TRIPS for patents on medicines, but TRIPS is relevant also for other health areas, which the WTO tobacco case between Australia and tobacco-producing countries illustrates. The best students should refer to this.

b) What separates: (i) "international trade law" from "global health law"? and (ii) "global health governance" from "global health law"?

International trade law is first and foremost related to the WTO and its dispute settlement mechanism and many trade agreements. International trade law is thus characterized by one

single dominant regulatory regime (WTO) and by a strong enforcement mechanisms included in this regime. Global health law can be defined narrowly or broadly. A narrow definition is: "legal norms, processes, and institutions that are designed primarily to attain the highest possible standard of physical and mental health for the world's population". A broad definition includes other parts of international law that affect global health (labour law, environmental law, trade law etc.), i.e. all laws that affect health. Global health law is characterized by not being an organized legal system with a unified treaty-monitoring body (such as the WTO). Instead, it consists of a network of treaties and soft law instruments that affect global health – many under the auspices of the WHO. A key feature of global health law is the negotiation, adoption and monitoring of normative rules (binding and non-binding) among countries, thus creating norms, mobilizing resources, guiding stakeholders to work collaboratively, and ensuring accountability for results. WHO is the most important institution for negotiating international health agreements (both soft law, such as recommendations and standards, and hard law, such as IHR and FCTC). Global health governance can be defined as "…the use of formal and informal institutions, rules, and processes by states, intergovernmental organizations, and non-state actors to deal with challenges to health that require cross-border collective action to address effectively". One core difference between global health law and global health governance is that the latter is process-oriented, includes global health law as only one of the tools used to protect and improve health, and that it includes non-state actors in this process.

c) Provide a short account of the basic content and meaning of the concept of "human right to health" found in the United Nations' legal framework. Refer to relevant agreements/legal tools.

The students should refer to the establishment of the UN in 1945, the adoption of the United Nations Charter, the purpose of maintaining international peace and security, and the purpose of achieving international co-operation in solving international problems of an economic, social, cultural, or humanitarian character, and in promoting and encouraging respect for human rights and for fundamental freedoms for all without distinction as to race, sex, language, or religion. This lays down the foundation for the Universal Declaration of Human Rights, 1948, where the right to life and health is included as part of the human rights:

- **Article 3**
    - Everyone has **the right to life**, liberty and security of person.
- **Article 25**
    - (1) Everyone has the **right to a standard of living adequate for the health and well-being** of himself and of his family, including food, clothing, housing and **medical care and necessary social services**, and the right to security in the event of unemployment, **sickness, disability**, widowhood, old age or other lack of livelihood in circumstances beyond his control.

It is important to note that this is a non-legally binding document, but nevertheless provides the basis for the UN's development of a regulatory framework for protecting the human right to health. The major UN instruments in defining and protecting the right to healthcare are:

- International Covenant of Economic, Social, and Cultural Rights (ICESCR), 1966 (binding agreement)

- Art. 12(1): "…recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health"
- Core principles: to achieve accessibility, availability, and acceptability and quality of health services

- World Health Organization (WHO), 1948 – the WHO constitution includes among other things, these principles:
  - Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.
  - The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.
  - The health of all peoples is fundamental to the attainment of peace and security and is dependent on the fullest co-operation of individuals and States.
  - Unequal development in different countries in the promotion of health and control of diseases, especially communicable disease, is a common danger.
  - The extension to all peoples of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health.
  - Governments have a responsibility for the health of their peoples, which can be fulfilled only by the provision of adequate health and social measures.

The students are not expected to cover all the elements referred to above, but need to show that they understand the basic principles of the ´human right to health" and how these have been developed from the UN Charter through the Declaration of human rights, WHO and ICESCR. Some will also refer to CHARTER OF FUNDAMENTAL RIGHTS OF THE EUROPEAN UNION (2012/C 326/02) where Article 35 "Health care" states that "Everyone has the right of access to preventive health care and the right to benefit (c.f. non-discrimination) from medical treatment under the conditions established by national laws and practices." Extra points to those who include this reference.

d) Give a short account of the difference between the EU's Social Security Coordination mechanism and the EU's Patients' Rights Directive.

- ***EU's Social Security Coordination***

This mechanism gives access to medically necessary, state-provided healthcare during a temporary stay in any of 28 EU countries + Iceland, Lichtenstein, Norway and Switzerland, under the same conditions and costs as people insured in the country they are visiting. This mechanism does not necessarily cover your costs if you are travelling for the express purpose of obtaining medical treatment (c.f. planned treatment) – if so, need authorization from national competent authority. It does not guarantee free services – services that cost nothing at home might not be free in another country.

- The rules for coordination of national social security systems fall within the framework of **free movement of persons** and should contribute towards improving their standard of living and conditions of employment

- It is necessary to **respect the special characteristics of national social security legislation** and to draw up **only a system of coordination**.
- It is necessary, within the framework of such coordination, to guarantee within the Community **equality of treatment under the different national legislation for the persons concerned**.

People who fall under the scope of this mechanism and meet the conditions are covered as…

- …though they were insured under the statutory system of the Member State where they are treated, at the expense of the competent Member State (the state where the person works and pays social security contributions)

Some students will also refer to the European Health Insurance Card (EHIC), which is relevant. EHIC cards are issued by the national health insurance providers. EHIC represents a proof that a person is an 'insured person' within the meaning of Regulation (EC) No 883/2004 and entitles the holder to be treated on the same terms as other persons insured within the public health system of the Member State of stay. EU law does not restrict Member States on payment other than the requirement that all persons covered are treated equally = if nationals have to pay, the persons seeking treatment with the EHIC will have to pay too – if nationals receive reimbursement, patients having shown an EHIC are reimbursed.

- ***EU's Patients' Rights Directive***

In a series of Court rulings late 1990s/2000s (e.g. *Kohll and Decker*, *Geraets-Smits and Peerboms; Watts)*, the Court confirmed that fundamental principles of free movement of goods, persons and services apply to (cross-border) health care. Court proceedings came as a result of individual citizens bringing the cases to Court and arguing that applications for prior authorization **were unduly** rejected. The implicit consequence of the rulings was that Case Law imposed restrictions on the discretion of Member States to grant/reject prior authorization for healthcare provision abroad = Member State control of health care management came under stress. Member States were thus concerned with the Court's advancement of free movement principles into their national health care territory. At the same time the member states couldn't ignore Court rulings because they were based on primary law (Treaty base). Decision-making was then moved from the judicial to the political sphere – EU Commission started preparing new legislation on cross-border care. In 2008, the European Commission presented a draft proposal for a directive on the application of patients' rights in cross-border health care ("Patients' Rights Directive"). In 2008 – 2011 there were intense discussions within the EU (European Parliament, member states/Council of the European Union) on the actual wording of the Directive. In 2011, the European Parliament and the Council in 2011 agreed on ***Directive 2011/24/EU on the application of patients' rights in cross-border healthcare*** **–** deadline for implementation in Member States was set to *25 October 2013*.

The Directive codifies some of the Case Law, such as the right to seek treatment abroad and be reimbursed by national authorities. Moreover, it confirms the difference between in-patient/out-patient care and the need for prior authorization to be limited to what is necessary, proportionate and non-discriminatory. However, the Directive also modifies parts of

established Case Law. For example, the range of health services subjected to a prior authorization system is extended. Thus, at least some of the member states' discretion and control is reinstated.

The Patients' Rights Directive gives patients in 28 EU countries + Iceland, Lichtenstein, Norway the right to seek treatment (and be reimbursed for it) in the other countries on the same conditions and costs as in they would have received in their home country.

- (…) costs of cross-border healthcare shall be ***reimbursed or paid up to the level of costs that would have been assumed by the Member State of affiliation***, had this healthcare been provided in its territory, without exceeding the actual cost of the healthcare received.
- Art. 7(9) permits Member States to ***limit application of the rules on reimbursement*** of cross-border healthcare ***for overriding reasons of general interest***
- Art. 7(11) requires such ***limitations to be necessary and proportionate***, and not to constitute a means of arbitrary discrimination or an unjustified obstacle to free movement
- National authorities can introduce a system of "prior authorization" for going to another Member State for treatment in 3 cases:
  - (i) for healthcare which involves overnight hospital stay of at least one night
  - (ii) for highly specialized and cost-intensive healthcare
  - (iii) in serious and specific cases relating to the quality or safety of the care provided by the particular provider in question
- Members required to inform publicly which treatments are subject to authorization

- **The use of Prior Authorization**
  - any system of prior authorization shall be restricted to:
    - what is ***necessary and proportionate*** to the objective to be achieved,
    - …and may not constitute a means of arbitrary discrimination or an unjustified obstacle to principles of free movement

The Directive also has rules, which require the member states to provide information to their national citizens about their rights under the Directive. The member states are required to set up National Contact Points to, among other things, to enhance the availability of information.

e) What are the main sources of international law? Provide a short account of the relationship between "international law" and "state sovereignty" and the possible implication of the defense of "state sovereignty" for the implementation of global health law.

Sources of international law are stated in the Statutes of the International Court of Justice (c.f. Art.38(1):

- ***International conventions or treaties*** – the (normally) written agreements

- ***Customary international law*** – describes the rules derived from general practice, based on the perception of a legal requirement, among states in international relations – binding on all states.
- ***General principles of law*** – principles, such as "good faith", recognized by civilized nations, which is binding on all states.
- ***Judicial decisions and literature*** – for example of international tribunals, and the writings of eminent scholars; these help to determine the existence and the interpretation of these several types of binding rules.

The students should refer to these sources and give a short description of what they mean. National sovereignty can be defined as the "right or capacity of countries to determine own affairs". More specifically, national sovereignty is the right of the supreme political authority – usually a government – to unqualified and unrivalled authority over its people and land. The problem of the defense of national sovereignty for the implementation of global health law refers in particular to the problem of enforcing international rules, which face opposition in nation states. Defense of national sovereignty can also create problems of negotiating and agreeing upon international health agreements. This may in fact provide some of the explanation of why the WHO so far has negotiated only two binding international agreements (IHR and FCTC). In this context it is also relevant to bring in the concept of health sovereignty, i.e. the exercise of a state's sovereign power to protect and promote health and provide health services. There is thus a potential conflict between the choice of either protecting national health sovereignty or alternatively protecting the universal 'right to health'. In this context, one debate is about whether the WTO's trade agreements hurt or help WHO Member States to exercise their health sovereignty. How can the WHO "match" strong Treaty organizations such as the WTO? Does the WHO need more "teeth"? Those students who bring in such elements in the discussion should be rewarded.

Appendix 1: Recommended norms for setting grades

Criteria adopted by the National Academic Board for political science on 27 October 2005 for specific degree courses and Master's theses.

Grade	General qualitative description (Norwegian Association of Higher Education Institutions/UiO)	Description of grades for Bachelor's degree courses (political science)	Description of grades for Master's degree courses (political science)	Description of grades for Master's theses (political science)
A **Excellent**	**Excellent performance, clearly outstanding. The candidate demonstrates excellent judgement and a high degree of independent thinking.**	The candidate demonstrates an excellent mastery of the course curriculum. When discussing subject-related issues, the candidate applies concepts, theories and empirical knowledge with a very high degree of certainty and in a manner that shows independent thinking and reflection. Correct use of sources and References.	The candidate shows exceptionally wide and solid knowledge of the course subject matter, and demonstrates an excellent ability to apply this knowledge in an independent manner.	An excellent thesis with an original analysis in which the research question is extremely well founded in the literature of the field. The thesis is also clearly outstanding in its use of methodology and its presentation of the material.
B **Very good**	**Very good performance. The candidate demonstrates very good judgement and degree of independent thinking.**	The candidate demonstrates very good mastery of the course curriculum. When discussing subject-related issues, the candidate applies concepts, theories and empirical knowledge with a high degree of certainty and in a	The candidate shows very wide and solid knowledge of the course subject matter, and demonstrates very good ability to apply this knowledge in an independent manner.	A very good analysis with a clear research question that is very well founded in the literature of the field. The thesis is also very good in its use of methodology and its presentation of the material.

Grade	General qualitative description (Norwegian Association of Higher Education Institutions/UiO)	Description of grades for Bachelor's degree courses (political science)	Description of grades for Master's degree courses (political science)	Description of grades for Master's theses (political science)
		manner that shows independent thinking and reflection. Correct use of sources and References.		
C **Good**	**Good performance in most areas. The candidate demonstrates good judgement and independent thinking with respect to the most important considerations.**	The candidate demonstrates good mastery of the course curriculum. When discussing subject-related issues, the candidate applies concepts, theories and empirical knowledge with certainty and in a manner that shows independent thinking. Correct use of sources and references in general.	The candidate shows wide and solid knowledge of the course subject matter, and demonstrates good ability to apply this knowledge in an independent manner.	A good thesis in all main respects. A clear research question and a well-conducted analysis that is well founded in the literature of the field. The thesis is also good in its use of methodology and its presentation of the material.
D **Satisfactory**	**Satisfactory performance, but with significant shortcomings. The candidate demonstrates limited judgement and independent thinking.**	The candidate demonstrates incomplete knowledge of the course curriculum. Concepts, theories and empirical knowledge are applied inconsistently, and there are some deficiencies in the use of sources and References.	The candidate shows variable knowledge of the course subject matter, and demonstrates some ability to apply this knowledge in an independent manner.	In general a good thesis with adequate analysis, but it also shows some weaknesses in formulating the research question, the research design, conducting the analysis, methodological skills or presentation.

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E **Sufficient**	**Performance that meets the minimum criteria, but no more. The candidate demonstrates very limited judgement and independent thinking.**	The candidate clearly demonstrates incomplete knowledge of the course curriculum, and shows substantial weaknesses in the application of concepts, theories and empirical knowledge, as well as a poor understanding when discussing subject-related issues.	The candidate shows poor knowledge of the course subject matter, and demonstrates a limited ability to apply this knowledge in an independent manner.	A thesis in which the analysis meets the minimum requirements set for academic presentation and discussion, but which demonstrates substantial deficiencies in formulating the research question, the research design, conducting the analysis methodological skills or presentation.
F **Fail**	**Performance that does not meet the minimum academic criteria. The candidate demonstrates a lack of both judgement and independent thinking.**	The candidate shows no mastery of even elementary parts of the course curriculum, and demonstrates wide gaps in knowledge or an erroneous representation and application of key concepts and theories.	The candidate shows very poor knowledge of the course subject matter, and demonstrates an inability to meet the minimum requirements set for the learning objectives of the course.	A thesis in which the analysis does not meet the minimum requirements set for scientific presentation and discussion. It also shows very substantial deficiencies in formulating the research question, the research design, conducting the analysis, methodological skills, use of citations or presentation, or does not satisfy the minimum standard of research ethics.