

Guidance for evaluating exams – HLAW4100 – fall 2019

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: What are the basic purposes of the United Nations (UN)? How has the human "Right to health" developed within the UN system? Describe the difference between soft and hard law and relate the development of the 'Right to health' to soft law and hard law agreements respectively (both the European Union (EU) and the UN are relevant here). Discuss the problems of protecting the human 'Right to health' by referring to factors at both the national level and global level, including the role of international organizations. Include the relevance of the concept of 'sovereignty' in this discussion.

Use the title: ***Right to health, United Nations and WHO***

Article 1 (1) of the United Nations' Charter states the purpose as "To maintain international peace and security, and to that end: to take effective collective measures for the prevention and removal of threats to the peace, and for the suppression of acts of aggression or other

breaches of the peace, and to bring about by peaceful means, and in conformity with the principles of justice and international law, adjustment or settlement of international disputes or situations which might lead to a breach of the peace;”. Students must be able to refer to the basic purpose of maintaining peace and security. Good answers will be able to refer to the UN Charter and link the ‘right to health’ to threats to peace and security, including reference to 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 (Article 1(3)). This leads up to the further development of the ‘right to health’ within the UN system. Here the students are expected as a minimum to be able to refer to the Universal Declaration of Human Rights (1948), the International Covenant of Economic, Social, and Cultural Rights (ICESCR) (1966) and the World Health Organization (WHO). Good answers will include specific references to these. The right to life and health is included as part of the human rights in the Universal Declaration of Human Rights – articles 3 and 25 in particular:

– **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.

Students are expected to refer to the Universal Declaration of Human Rights as a non-binding document (and thus as soft law). Good answers will recognize that the Declaration functions as a basis for the UN’s development of frameworks for protecting the human right to health. Core elements are included in the International Covenant of Economic, Social, and Cultural Rights (ICESCR), as well as in the WHO. Students are expected as a minimum to separate between hard law agreements as binding and soft law agreements as non-binding. Good answers will problematize how different hard law and soft law agreements work by referring to the problems of enforcement and compliance mechanisms. This is particularly relevant for many health-related hard law agreements.

Students should be able to refer to ICESCR as a binding agreement and thus as hard law. Good answers will refer to specific elements of the Covenant relevant for the ‘right to health’, and the principles underlying the work on protecting this right such as:

- 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

Good answers will also be able to describe the role of the WHO (1948), its core functions (and objectives) and its relevance for the ‘right to health’. The WHO is 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. The WHO constitution includes among other things, the following principles, which definitely is relevant for the development of the ‘Right to health’:

- 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.

Good answers will be able to refer to the role of the WHO as a specialized agency within the UN system and thus as one of the main 'tools' of the UN to protect the human 'right to health'. Some will include references to hard law agreements negotiated within the framework of the WHO – the WHO's Framework Convention on Tobacco Control (FCTC) and the International Health regulations (IHR), which is relevant. As to the development of the human 'right to health' in the EU, it is expected that answers include references to the CHARTER OF FUNDAMENTAL RIGHTS OF THE EUROPEAN UNION (2012/C 326/02) and that this was originally a non-binding document (soft law), but became binding (hard law) when the Treaty of Lisbon entered into force in December 2009. Really good answers may refer to specifics of the Charter, such as Article 35 "Health care", which 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." It is also relevant to refer to the 'public health provision' - Article 168 of the Lisbon Treaty (ex Article 152 TEC), which among other things states, that, "A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities". Very good answers may link the development of the 'right to health' in the context of UN with the development in the context of the EU. Some will also include a more general discussion of the development of the EU's health laws and policies (such as cross-border care, food law, medical device, pharmaceuticals etc.), which basically is not that relevant here. Thus, such a discussion will not give many extra points, except if there are convincing arguments on how this relates to the protection of the human 'right to health'.

When discussing the problems of protecting the human 'right to health' many relevant elements can be included. Good answers must include factors at both the national level and global level. Relevant elements are: problems of enforcement/compliance mechanisms under international agreements/international organizations, problem of funding (including funding earmarked by donors), differences in capacity/resources at the national level (including know-how, infrastructure etc.), developed vs. developing countries, different interests, rise of non-governmental actors, which are hard to govern, differences in how the "right to health" is interpreted, and cultural differences. In lectures, the following points have also been 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...

Good answers must problematize the concept of 'sovereignty' in this context, i.e. how a strengthening of international organizations/enforcement mechanisms may be perceived as a threat against national sovereignty. They should also be able to refer to differences between different international organizations (UN/WHO, WTO, EU) as to their capacity to enforce international law (or EU law in the case of the EU) – thus 'threatening' national sovereignty. It is important to note that the EU stands out in this context as to its supranational character and as to how much sovereignty member states have delegated to the EU-level

B. Give a short account of the basic elements of cross-border care. Describe the EU's free movement principles and relate them to the core elements of cross-border care in the EU/EEA area. Discuss the EU's role in health policy and law with reference to both patients' rights and the need to protect the functioning of the internal market. Include the concepts of Treaty law, supranational, and national sovereignty in the discussion.

Use the title: ***EU, cross-border care and free movements***

Basically, cross-border care can be characterized as including all aspects of the health sector, which have cross-border aspects (treatment abroad, patient mobility, common authorization of medicines, common standards for medical devices, mutual recognition of qualifications for health personnel etc.). Good answers will recognize this and thus problematize the meaning of cross-border care. Still, in this context, the core elements (which are highlighted in syllabus, as well as in lectures) expected to be included in the answer are the Social Coordination Mechanism and the Patient Rights Directive. Some will also mention contractual arrangements allowing patients to be treated in hospitals in other countries, which is a plus.

Students must be able to identify the free movement principles of the EU's internal market: 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). They should also recognize that these principles are Treaty-based (included in the Treaty of Rome) and thus are part of the EU's *primary law*, which refer to the supreme source of law in the EU, i.e. laws at the top of the European legal order. The internal market encompasses the EU's 28 member states (soon 27, c.f. Brexit). Students should be able to mention that the internal market, with some exceptions, is also extended to Norway, Iceland and Liechtenstein through the EEA Agreement, and to Switzerland (with some exceptions) through bilateral agreements. The Social Security Coordination applies to all of these – the Patient Rights Directive applies to all except Switzerland. The internal market is part of the core goal of the EU of progressive integration of Member States' economic and political systems. The students are expected to relate these principles to the core elements of cross-border care.

Good answers go back to the Treaty of Rome of 1957, which lay down the foundations for the coordination of social security among the member states (and thus cross-border care) through

the principles of free movements and through the provisions on social policy. The principles of free movement imply prohibition of “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 cross-border care regulation. 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 attempting to achieve a well-functioning single European market. The intensified work on the single European market project triggered the development of common health rules and policies in the EU (including aspects related to cross-border care) 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 discussion, the students should demonstrate that they understand the principles of free movement, and how these freedoms are linked to the development of rules on cross-border care, such as Social Security Coordination (particularly relevant for free movement of people) and Patients’ Rights Directive (particularly relevant for free movement of services). They should also demonstrate an understanding of “spill-over effects”, i.e. how cross-border care (Patients’ Rights Directive in particular) has been affected by EU’s internal market regulation even though patient mobility 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. When discussing cross-border care, good answers will 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 States, 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 some of 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 must be in line with these principles.

The assignment states that the students should discuss the role of the EU in health policy and law *with reference to both patients’ rights and the need to protect the functioning of the internal market*. Thus, in the discussion, the relationship between cross-border care (c.f. patients’ rights to treatment) and the internal market regulation should be central. However, bringing in other elements may give extra points as long as these elements are related to patients’ rights/internal market regulation. Good answers are expected to describe and discuss the two core elements of cross-border care in more detail: *EU’s Social Security Coordination* and *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/working/living. 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 patients 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)

Students should also refer to the European Health Insurance Card (EHIC). 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. Good answers should be able to link the development of the Social Security Coordination back to the treaty of Rome, the principle of free movement of persons and thus the goal of establishing a free market for workers within the borders of the EU. In fact, in the Treaty of Rome under TITLE III FREE MOVEMENT OF PERSONS, SERVICES AND CAPITAL, CHAPTER 1 WORKERS, article 51 states:

ARTICLE

51

The Council shall, acting unanimously on a proposal from the Commission, adopt such measures in the field of social security as are necessary to provide freedom of movement for workers; to this end, It shall make arrangements to secure for migrant workers and their dependants:

1. (a) aggregation, for the purpose of acquiring and retaining the right to benefit and of calculating the amount of benefit, of all periods taken into account under the laws of the several countries;
2. (b) payment of benefits to persons resident in the territories of Member States.

Students are not expected to refer to all the details here, but good students will be able to link the Social Security Coordination to the Treaty of Rome, free movement of persons and the goal of the EU of establishing a common labor market.

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. Students should be able to link the development of the Patients' Rights Directive to the principle of free movement of services in particular (the right of citizens to seek health services in other countries and be reimbursed by home country) and thus also mention that because of the link to primary law, the member states have more or less been 'forced' to accept these rules. In this context, the students should be able to link the competencies of the EU (c.f. supranational) to competencies of the member states (c.f. national sovereignty). Good answers will relate this discussion to article 168 of the Lisbon Treaty, in particular paragraph 7:

7. 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. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them.

The question then is which parts of cross-border care fall under the responsibility of the member states (organisation and delivery of health services and medical care) and which parts fall under the responsibility of the EU (c.f. functioning of the internal market, free movement principles). Very good answers include these elements in the discussion with reference to Treaty Based law (c.f. primary law), the supranational character of the EU (c.f. EU competencies, EU's law-making) and national sovereignty (c.f. areas still under the responsibility of member states).

Question 2:

Answer three of the following questions:

a) *What are the main sources of international law? Give a short account of some key differences between the systems for national law and the systems for international 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. As to the differences between the systems for national law and the systems for international law, the students should be able to refer to the anarchic (and horizontal) nature of the international

system where (basically) there are no supreme authority in place for law enforcement. Moreover, international law is primarily about the set of rules, norms, and standards generally accepted in *relations between nations* (and to a limited degree directed towards international organizations and to a very limited degree directed towards individuals). National systems of law are sets of rules, norms, and standards directed towards all aspects of the society. Moreover, national systems are hierarchical and have supreme authority for law enforcement, compliance and use of force (Courts, police force etc.). In this context it is also relevant to bring in the concept of national sovereignty, i.e. the “right or capacity of countries to determine own affairs”. National sovereignty is basically the right of the supreme political authority – usually a government – to unqualified and unrivalled authority over its people and land. This authority (and accountability) is lacking in the international system.

b) Give an account of how Tobacco Control is relevant under the World Trade Organization (WTO) and the World Health Organization (WHO) respectively.

A good starting point for the answer is to separate between tobacco control as a ‘trade restriction’ relevant under the WTO and as a instrument for health protection under the WHO. Good answers will refer to the different main purposes of the two organizations (WTO = trade liberalization/trade regulation – WHO = health promotion and health protection). Thus, 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). 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 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 and other product standards). 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 c 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 tobacco control is regulated in the WTO and WHO respectively. Many students will use the so-called “WTO Tobacco Case” (2014) between Australia on one side and Honduras, Indonesia, Dominican Republic and Cuba on the other to illustrate the regulation of tobacco control. This is ok depending that the students are able to refer to the specifics of how tobacco control is regulated under the WTO and WHO (see above). They should also be able to demonstrate that they understand that this dispute was about examining whether Australia’s tobacco control measures were in *breach of WTO rules* (even though FCTC was used by Australia as ‘scientific’ justification for these measures). The background for the 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. 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 – FCTC. 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
- WHO’s Framework Convention on Tobacco Control important as part of the scientific evidence in support of Australia’s measures

The students are not expected to describe all these elements, but should be able to refer to the basics of the relevance of tobacco control under the WTO and WHO (including the differences in regulation under these different regimes).

c) Give a short description of key elements of the WTO’s TRIPS (Trade-related Intellectual Property Rights) agreement and show how this agreement can affect the price and availability of medicines.

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.

d) Give an account of the proportionality principle. Use examples from the health sector.

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. The principle can for example be used in the assessment of whether trade restrictions are appropriate to justify a certain objective (such as health protection). In the EU, it can for example justify state intervention to protect national health systems based on exceptions from the EU’s internal market rules because of health as a general interest and legitimate concern. It is important that the students understand that this is a *general legal principle*, which is relevant in many contexts. Some examples of the use of the proportionality principle:

- **Treaty on European Union and the Treaty on the Functioning of the European Union**
 - Article 5(4); Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties.
- **EU General Food Law:**
 - In accordance with the principle of proportionality as set out in Article 5 of the Treaty, this Regulation does not go beyond what is necessary in order to achieve the objectives pursued,
- WTO SPS Agreement

- Article 2(2): Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health

Students can choose to use among a large number of relevant examples from the health sector, including Tobacco control, Patients' Rights Directive, food safety regulation in the EU etc. The important thing here is that they demonstrate both the core (general) elements of the principle (balance between a restriction imposed by a corrective measure and the severity of the nature of the prohibited act) and how this is relevant for health law/health policy.

e) Provide an account of the meaning of 'global health governance' and 'global health law'.

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.

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.

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)
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.

