

Question 1

Indicate which statement is true

1. We spend on average annually 1,4% of the GDP on healthcare
 2. The main idea of adaptive pathways is that new drugs reach the market faster, so that very large patient populations can benefit
 3. When generics enter the market, prices should normally go down. We see, however, that this economic principle of supply and demand, does not apply to the healthcare market
 4. In Belgium, our out-of-pocket expenditures are higher than in France, however, far less than the out-of-pocket expenditures in the US
 5. Value-based pricing is difficult since variation exists across indications or patient groups
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- a. All statements are true
 - b. None of the statements is true
 - c. Statement 1 & 2 are true
 - d. Statement 3, 4 & 5 are true
 - e. Statement 2, 3 & 5 are true

The correct answer is d.

FEEDBACK:

- We spend on average annually 1,4% of the GDP on healthcare. FALSE. On average, 10% of GDP is spent on healthcare annually.
- The main idea of adaptive pathways is that new drugs reach the market faster, so that very large patient populations can benefit. FALSE. Adaptive pathways, and the adaptive licensing of drugs, has been designed to allow timely access to innovative drugs in **targeted patient populations**.
- When generics enter the market, prices should normally go down. We see, however, that this economic principle of supply and demand, does not apply to the healthcare market. TRUE. The introduction of generics cuts average price by 50%. However, the total volume sold goes down, because advertising goes down in favor of new, more expensive products: Castanheira et al. (2019). Normally, when generics enter the market, the branded drug price should go down. However, research indicated that the economic principle of supply and demand does not apply when it comes to the drug market: the volume sold goes down and prices go up since newer – more expensive – drugs are heavily advertized.
- In Belgium, our out-of-pocket expenditures are higher than in France, however, far less than the out-of-pocket expenditures in the US. TRUE
- Value-based pricing is difficult since variation exists across indications or patient groups. TRUE

Question 2

Indicate which statement is true

1. It is difficult to compare drug prices internationally: there are multiple products, a nonlinear pricing, a lack of transparency, different prescription patterns (even with similar GDP per capita), and further also issues like dosage/package size
2. The big pharmaceutical companies have since years an annual risk-adjusted ROI that is too excessive with respect to other sectors
3. Both the regulatory system, as well as the patent system, rewards marginal innovation. This leads to distorted price settings for drugs that are not 'true' innovations.

- a. All statements are true
- b. None of the statements is true
- c. True – false – true
- d. False – true – false
- e. True – true – false

The correct answer is a.

FEEDBACK:

- 1. It is difficult to compare drug prices internationally: there are multiple products, a nonlinear pricing, a lack of transparency, different prescription patterns (even with similar GDP per capita), and further also issues like dosage/package size. TRUE
- 2. The big pharmaceutical companies have since years an annual risk-adjusted ROI that is excessive with respect to other sectors. TRUE: an annual risk-adjusted ROI of 3% in excess of the market is too high, see Thakor et al (2015).
- 3. Both the regulatory system, as well as the patent system, rewards marginal innovation. This leads to distorted price settings for drugs that are not 'true' innovations. TRUE: the existing regulatory system is biased against 'creative innovation' by excessively rewarding 'marginal innovation' (see Fojo et al. 2014 for evidence on cancer therapies). Further, also the patent system is abused in this respect (e.g. by nearly unlimited potential rewarding of supplementary protection certificates SPCs).

Question 3

Only one correct answer

When filing for a patent, you need to make a **X** analysis which means digging into the **Y** to make sure that you are not infringing third party's patents rights (pending).

- a. X = State of the art; Y = scientific literature
- b. X = freedom to operate; Y = state of the art
- c. X = novelty; Y = freedom to operate
- d. X = non-obviousness; Y = state of the art
- e. X = patentability; Y = patent portfolio

The correct answer is b.

Question 4

Multiple answers are possible

The conditions to grant a patent are:

- a. novelty
- b. non-obviousness
- c. industrial application
- d. patentable subject matter
- e. pay the fees

The correct answer is a, b, c, d, e.

Question 5

Indicate which statement is true

1. The medicines patent pool (MPP) is a patent pool aiming to bring HIV/AIDS therapies to people in the low and middle-income countries (LMICs).
2. Trade secrets are highly important in the company, and form the base of the company's innovative product.
3. When filing for a patent, proving non-obviousness is more difficult than proving novelty.
4. The EU and US term of patent, provided that maintenance fees are paid in time, is maximum 20 years from the filing date of the patent application. This means that the return on investment (ROI) of the company, when its product is granted a market authorization, last for 20 years.
5. An explicit and written consent of the subject is always needed for the processing of the data unless processing is done for purposes of public health, unless one has for scientific research purposes or the presumed consent is applicable with a positive advice of ethics committee

- a. All statements are true
- b. None of the statements is true
- c. True – false – true – true - false
- d. False – true – false – true – false
- e. True – true – false – true - true

The correct answer is e.

FEEDBACK:

1. The medicines patent pool (MPP) is a patent pool aiming to bring HIV/AIDS therapies to people in the low and middle-income countries (LMICs). TRUE
2. Trade secrets are highly important in the company, and form the base of the company's innovative products. TRUE
3. When filing for a patent, proving non-obviousness is more difficult than proving novelty. Novelty is proven when no prior art can be found. To prove an inventive step, you need to show that an invention is not something that a person having ordinary skills in the art (PHOSITA) could have easily invented when combining the existing products or methods that are part of the state-of-the-art.
4. In the US the term of patent, provided that maintenance fees are paid on time, is maximum 20 years from the filing date of the patent application. Meaning that the ROI of the company, when its product is granted a market authorization, last for 20 years. FALSE. The company ask for a patent before the development of its product, the company develops its product during the patent duration meaning that the longest the clinical trial is, the smaller the ROI will be.
5. An explicit and written consent of the subject is always needed for the processing of the data unless:
 - processing for purposes of public health
 - for scientific research purposes (in accordance with article 89)
 - presumed consent is applicable with a positive advice of ethics committee