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„Trade related challenges to the right to health care in the European Union“

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Abstract

The aim of this thesis is to identify, describe and evaluate the most current and pressing trade-related challenges to the right to health care in the European Union. In my thesis, I examine whether there is a causal link between shortages of medicinal products and the parallel import and export of medicinal products and whether parallel trade is related to illegal pharmaceutical distribution chains. My thesis consists of an analysis of the economic paradigm behind the parallel trade, I evaluate theoretical approaches and empirical data on the benefits of parallel trade. I present a case study of practices behind parallel trade, which include cartel behavior of pharmaceutical distributors and pseudo-pharmacies, limitation of access to medicinal products for regular pharmacies and corruption practices in the distribution of medicinal products in Czech pharmaceutical market. The findings of my thesis are that the European Union by uncritical support to parallel trade violated the right to health care in article 35 of the Charter of Fundamental Rights of the European Union because it did not ensure a high level of human health protection in the definition and implementation of all the Union's policies and activities.

Keywords: Right to health care; parallel trade; parallel import and export; medicinal products; shortages of medicinal products; illegal distribution of medicinal products; health law; human rights

Abstrakt

Ziel dieser Arbeit ist es, die aktuellsten und dringendsten handelsbezogenen Herausforderungen für das Recht auf Gesundheitsversorgung in der Europäischen Union zu identifizieren, zu beschreiben und zu bewerten. In meiner Diplomarbeit untersuche ich, ob ein kausaler Zusammenhang zwischen dem Mangel an Arzneimitteln und dem Parallelimport und -export von Arzneimitteln besteht und ob der parallele Handel zu illegalen Vertriebsketten für Arzneimittel führt. In meiner Masterarbeit wird das Wirtschaftsparadigma hinter dem Parallelhandel analysiert. Dabei werden theoretische Ansätze und empirische Daten zu den Vorteilen des Parallelhandels bewertet und eine Fallstudie über Praktiken hinter dem Parallelhandels präsentiert. Diese Fallstudie umfasst das Kartellverhalten von Pharmahändlern und Pseudoapotheken, und die Einschränkung

des Zugangs zu Arzneimitteln für reguläre Apotheken und Korruptionspraktiken bei der Verteilung von Arzneimitteln auf dem tschechischen Pharmamarkt. In meiner Masterarbeit komme ich zu folgendem Ergebnis: die Europäische Union hat durch unkritische Unterstützung des Parallelhandels das Recht auf Gesundheitsversorgung ,wie es in Artikel 35 der Charta der Grundrechte der Europäischen Union dargelegt ist, verletzt, weil sie hat weder in der Definition noch in der Umsetzung aller Richtlinien und Aktivitäten ein hohes Maß an Schutz der menschlichen Gesundheit gewährleistet.

Schlagwörter: Recht auf Gesundheitsversorgung; Parallelhandel; Parallelimport und Parallelexport; medizinische Produkte; Mangel an Arzneimitteln; illegale Verteilung von Arzneimitteln; Gesundheitsgesetz; Menschenrechte

Pledge of Honesty

On my honour as a student of the University of Vienna, I submit this work in good faith and pledge that I have neither given nor received unauthorized assistance on it.

Vienna, 27 July 2020

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List of Abbreviations

CFR Charter of Fundamental Rights of the European Union

EC European Commission

EP European Parliament

EU European Union

FMD Falsified Medicines Directive

GC General Comment

GSK GlaxoSmithKline

ICESCR International Covenant on Economic, Social and Cultural Rights

TEC Treaty establishing the European Community

TFEU Treaty on the Functioning of the European Union

UN United Nations

Introduction

As a student of law, economics and philosophy, I was always interested in public health. I started my own pharmacy in Brno, Czechia in order to get practical insights into how the pharmaceutical market operates. Being a student of law, I soon realized that something is not alright. Since 2014, I encountered various types of practices, which I would—without hesitation—call against the legal interest of patients to the highest standard of attainable health. They all had several shared features:

1. they were connected to the parallel trade on the Internal market of the EU;
2. the main actors involved in these practices were operating in a number of member states of the EU;
3. people who were involved in these practices presented them as a purely legal way of conduct;
4. national institute for drug control (regulative authority) in Czechia was incapable of any systematic action.

When I started to examine what is, in reality, going on in the pharmaceutical market, it became clear that there are significant trade-related challenges to the right to health care at the level of the European Union.

The EU holds an ambivalent role in public health. It has high ambitions and through the regulation of trade, it has a very strong position in how the pharmaceutical market is regulated. However, it still needs to keep health policy as a Cindarella of policymaking. The Union cannot disclose its beauty, otherwise, all other member states would like to marry her. The Union in its founding treaties acknowledged the importance of health policy but at the same time, it could not claim exclusive competence, as the member states would never allow the Union to take the direct lead. Health policy is too important, to let it fully escape from national policymaking reach. Nevertheless, as I will show in the chapter focused on the historical perspective, the role of the Union constantly grows. This trend is observable after the Maastricht Treaty and after the Treaty of Lisbon.

In the last years, several member states of the EU faced severe shortages of important medicinal products. In light of the recent COVID-19 pandemic crisis, the shortages of

medicinal products were even more highlighted. On its last session, the ENVI Committee of the European Parliament prepared a draft report on the motion for a resolution to call on the Commission for action at the EU level, otherwise, the situation with the availability of medicinal products in several member states of the EU will become a structural problem.

In my thesis, I will examine whether there is a causal link between shortages of medicinal products and parallel import and export of medicinal products and whether parallel trade leads to other shortcomings of the pharmaceutical market including illegal practices, which have overall consequences on the right to health care stated in article 35 of the Charter of Fundamental Rights of the European Union.

I will especially focus on these questions: Does parallel import and export of medicinal products within the Internal market of the EU lead to shortages of medicinal products in the member states? Do legal instruments of the EU in the field of parallel import and export of medicinal products violate article 35 of the Charter of Fundamental Rights of the European Union on the right to health care? Do policy instruments against falsified medicines effectively prevent illegal distribution chains? Do illegal distribution chains violate article 35 of the Charter of Fundamental Rights of the European Union on the right to health care?

Description of the methodology, research design

I will use mainly qualitative research methods, especially theoretical analysis. First of all, I will establish a theoretical framework for my thesis. For the theoretical framework of my thesis, on trade-related aspects of the parallel import and export of medicinal products, I will base my thesis on the conceptualization of the trade-related issues delimited in the edited book *Law of Competition and Trade in the Pharmaceutical Sector* (2019) and Petit's chapter 'Parallel Trade: econ-oclast thoughts on a dogma of EU competition law', in I. Govaere, R. Quick and M. Bronckers (eds.), *Trade and Competition Law in the EU and Beyond* (2011). On the right to health care and public health aspects of EU law, I will use the *European Union Health Law: Themes and Implication* (2015).

I will critically assess the conceptualization of the topic developed by the authors mentioned above and evaluate whether the current challenges specified in the description on my thesis constitute a violation of the right to health care. In order to evaluate whether the challenges specified in my topic constitute a violation of the right to health care, I will theoretically analyze the right to health care. Thus, part of the theoretical analysis is the analysis of the normative cope of the right to health care and the right to health.

For theoretical analysis of legislative acts and case law at the EU level, I will need information mainly from the European Union's sources. Apart from EURLEX and other publicly accessible information sources, I will collect data also from the EPRS Unit (European Parliament) that provides comprehensive information on the topic.

I will conduct a case study in Czechia to examine the paradigm behind the parallel trade. I will secure data from various pharmacies to observe the behaviour of the biggest distributor of medicinal products and an active parallel trader, PHOENIX group. I will analyze the distribution of medicinal products and evaluate the practices that parallel traders use to get access to medicinal products. I will especially focus on the legality of practices used by parallel traders. I will evaluate the shortcomings of parallel trade.

1. The European Union and public health

1.1 Historical perspective

The European Union and public health have a peculiar relation, which needs to be understood with regards to the Union's ideological origins. If we leave the political intentions after the Second World War aside, the European Union and its predecessors—the European Coal and Steel Community and the European Economic Community—were primarily developed to facilitate the ideas of economic unity and free-market trade. Firstly by lowering trade barriers such as customs and tariffs within the ECC, later on by adopting more and more sophisticated legislation to actively promote trade.

The very first directive that aimed to regulate medicinal products was the Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products. It was triggered by several disasters related to insufficient evidence-based authorization of medicinal products.[1]

In the 1970s, a huge wave to promote the free movement of workers and professionals with added value resulted in the adoption of the popularly called *doctor's directive*.[2] This directive was adopted among other directives, which granted mutual recognition to highly skilled professions. The doctor's directive—under the condition that member states implement minimum quality requirements—guaranteed automatic mutual recognition of nearly all medical qualifications in the Union.[3]

[1] The European Commission, Legal framework governing medicinal products for human use in the EU © European Union, 1995-2020, https://ec.europa.eu/health/human-use/legal-framework_en (accessed 10 June 2020).

[2] Council Directive 75/362/EEC of 16 June 1975 concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in medicine, including measures to facilitate the effective exercise of the right of establishment and freedom to provide services (1975) OJ L 167.

[3] B. Duncan, 'Health policy in the European Union: how it's made and how to influence it', *The British Medical Journal*, vol. 324, no. 7344, 2002, pp. 1027–1030.

1.1.1 The Treaty of Maastricht

The turning point was the Maastricht Treaty in which the competences of member states and the EEC got into an intersection with no clear boundaries. 1.1.1 The Treaty of Maastricht explicitly stated in article 192 on public health that "the Community shall contribute towards ensuring a high level of human health protection by encouraging cooperation between the Member States and, if necessary, lending support to their action."[4] The Treaty of Maastricht also stressed that "health protection requirements shall form a constituent part of the Community's other policies."[5] Furthermore, it outlined quite indeterminately that the Commission has the power to come up with a useful initiative, in close contact with the Member States, to promote coordination of health policies among member states.[6]

However, the member states' fear that such an important policy would escape the national policymakers' reach resulted in restricting the Council to adopt only recommendations and incentive measures.[7] Thus, leading the dichotomy in public health policymaking, when the EU's main tools on how to influence public health were indirect.

1.1.2 The Treaty of Amsterdam

The Treaty of Amsterdam brought along further strengthening in health policy. Article 129 was reformulated stating that "a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities."[8] Although the reformulation of article 129 may not seem of such gravity to a layman, it brought significant obligations. Since the Treaty of Amsterdam, the Community is explicitly bounded to protect a high level of human health in all of its policies.

[4] Article 129 of the Treaty of Maastricht on European Union (1992) OJ C 191.

[5] Ibid, article 129.

[6] Ibid, article 129.

[7] Ibid, article 129.

[8] Article 129, Treaty of Amsterdam amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts (1997) OJ C 340.

Furthermore, the Treaty of Amsterdam strengthened complementarity of the Community action to national policies when it stated that "the Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education."[9]

Nonetheless, to underline once again the dichotomy of health policymaking, the member states negotiated a subparagraph 5 of Article 129 in a form of a proclamation that the Community shall fully respect their responsibilities for the organization and delivery of health services and medical care.[10]

Any harmonization of the laws and regulations of the member states was unacceptable. The Council was able to adopt only recommendations.[11]

After the Maastricht Treaty, the Commission was undergoing an era of restructuralization. In 1999 was created a directorate-general for health and consumer protection (DG SANCO), which remained functioning until 2014. DG SANCO fulfilled its role in numerous aspects. It established the first platform to engage with stakeholders on public health issues. It started assessment mechanisms on a range of public health issues and collected data for evaluative purposes. It established capacities to define health policies with regards to specific challenges but it seemed to be less successful in identifying a clear general strategy in public health and in implementation of the policies designed by DG SANCO.[12]

[9] Ibid, article 129.

[10] Ibid, article 129.

[11] Ibid, article 129.

[12] Clemens T., Sørensen K. Rosenkötter N., et al., 'The Directorate-General for Health and Consumers 1999–2014: An assessment of its functional capacities', Health Policy, vol. 121, 2017, pp.594–603.

DG SANCO was in 2014 substituted by the Commission's Directorate-General for Health and Food Safety (DG SANTE), which is responsible for EU policy on food safety and health and for monitoring the implementation of related laws.

Since the Treaty of Amsterdam strengthened the role of the European Union in health policy, the Union initiated several strategic policy programs focused on health policy starting with the EU Public Health Programme 2003-2008, which is periodically renewed (the Health Programme 2009-2013, and the Third Health Programme 2014-2020). The current EU health program was designed to help member states to tackle economic and demographic challenges their health systems are facing and empower citizens to take an active role in managing their health.[13]

1.1.3 The Treaty of Lisbon

With the Treaty of Lisbon, the ambivalent status of health policy remained. Nevertheless, the revision of the treaties in other aspects heralded that the Union is not fully satisfied only with complementing national health policies and to act at the level of shared competence aiming at activities to support, coordinate or supplement the actions of the member states.[14]

The Treaty of Lisbon added at the end of paragraph 1, the second subparagraph of previous article 152, the following: “and monitoring, early warning of and combating serious cross-border threats to health.”[15] Furthermore, it also extended the list of competencies in paragraph 2 with “initiatives aiming at the establishment of guidelines

[13] Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC (2014), OJ L 86.

[14] See the amendedment of article 152 Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community (2007) OJ C 306; Article 168 in Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union (2012), OJ C 326.

[15] Ibid, article 168 (ex article 152), paragraph 1, second subparagraph .

and indicators, the organization of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation."[16]

These two additions significantly extended the list of shared competences in health policy explicitly introducing monitoring and evaluation to be an essential part of health policy. Therefore, the Union gained a legislative basis to carry out systematic collection and analysis of information on practices and impact of public health actions.

Another improvement in the Treaty of Lisbon was a stronger emphasis on health services in cross-border areas. [17]

From the perspective of common safety concerns, measures setting high standards of quality and safety for medicinal products and devices for medical use were explicitly added to the objectives of paragraph 4.[18]

1.1.4 The Charter of Fundamental Rights of the European Union

The negotiations of the Treaty of Lisbon carried with it a major step in codifying the human rights of EU citizens in the European Charter of Fundamental Rights. As a part of the negotiations of the Treaty of Lisbon, it came into effect on 1 December 2009.

Bearing in mind that the European Union is an organization *sui generis*, it was evident that also the EU Charter of Fundamental Rights will be a very specific human rights instrument. Since the beginning, it raised many questions including the scope of application, enforceability, conflicts with national charters of human rights, the human rights instruments of the Council of Europe, etc. The Union strictly avoided to use the term human rights but it followed a German model of Grundrechte (fundamental rights).

[16] Ibid, article 168 (ex article 152), paragraph 2.

[17] Ibid, article 168 (ex article 152), paragraph 2, the first subparagraph.

[18] Ibid, article 168 (ex article 152), paragraph 4, point c.

In relation to the protection of citizens' health, it preserved the dichotomy described above. The right to health care is codified in article 35 of the Charter on Fundamental Rights:

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 the Union's policies and activities.[19]

In other words, the member states are the ones who set out the restrictions under which the right of access to preventive health care the right to benefit from medical treatment can be exercised. However, it is the Union that has the human rights obligations to the protection of a high level of human health in the definition and implementation of all the Union's policies and activities. Therefore, the Union is obliged to respect, fulfill and protect the right to health care in each and every legislative act it adopts but also broadly in all of its actions, e.g. actions of its agencies.

The wording of article 35 follows the values set out in Article 152 of TEC, which was during negotiations of the Treaty of Lisbon replaced by Article 168 of the Treaty on the Functioning of the European Union. The Union's human rights obligations have the same formulation as the first subparagraph of paragraph 1, Article 168 of TFEU. Apart from the Treaties, it is conceptually based on Articles 11 and 13 of the European Social Charter.[20]

1.1.5 EU Agencies

The most significant agency of the EU in the regulation of medicinal products is the European Medicines Agency. It was founded in 1995, to coordinate the work of existing national medicine regulatory bodies. The main objective of the EMA is to ensure—in line with article 168 of TFEU—a high level of protection of public health.

[19] Article 35 of the Charter of Fundamental Rights of the European Union (2012) OJ C 326.

[20] Council of Europe, European Social Charter (Revised), 3 May 1996, ETS 163.

From the practical point of view, the EMA fulfills a number of tasks related to the authorization of medicinal products. The EMA serves as the central agency for collecting, evaluating and publishing the clinical data that are essential for policymaking on medicinal products. Mainly it shall provide timely access to new medicinal products for patients. It evaluates applications for marketing authorization and hosts scientific committees, which provide impartial evidence-based recommendations on medicinal products for human and veterinary use. Furthermore, it monitors the safety of medicinal products across the member states, when it evaluates data from the national medicine regulatory bodies. However, the EMA does not regulate the prices of medicinal products nor their availability at distributors.[21]

Another agency of the EU in public health is the European Centre for Disease Prevention and Control (ECDC). The ECDC gained enormous attention during the COVID-19 pandemic crisis. Its role is to strengthen Europe's defenses against infectious diseases. Concerning medicinal products, it shall improve vaccine coverage in the EU.[22]

In 2005, the Executive Agency for Health and Consumers (EAHC) was created in order to effectively implement the EU Health Programme. The EAHC was later on transformed in the Consumers, Health, Agriculture and Food Executive Agency. It grew from a small agency on the EU scale and works closely with DG SANTE. It mainly focuses on the implementation of four objectives:

1. to promote health, prevent diseases and encourage supportive environments for healthy lifestyles corresponding to the 'health in all policies' principle,
2. protect Union citizens from severe cross-border health threats,
3. support innovations in health systems and their efficient and sustainable functioning

[21] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (2004) OJ L 136.

[22] Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 april 2004 establishing a European Centre for disease prevention and control (2004) OJ L 142.

4. ensure access to better and safer health care for EU citizens.[23]

1.2 The current state of health policymaking

If we take into considerations that there is no united European health care system, one can ask why is the European Union after all important?

The Union regulates the free movement of goods and services.[24] Through market regulations, the Union can influence the availability, distribution and indirectly also the prices of medicinal products in member states.

However, health policy has been always something in between the member states' national policymaking and the Union's ambitions to regulate it.[25] It does not belong to exclusive competences of the Union, but the Union is bound to respect public health in its policymaking.

Common safety concerns in public health matters for aspects stated in the Treaty on the Functioning of the EU belong to shared competence between the Union and the Member States.[26]

Additionally, the Union has the competence to carry out actions to support, coordinate or supplement the actions of the Member States with regards to the protection and improvement of human health.[27]

The ambivalence in health policymaking remains, although the Union has higher goals than what the wording of the treaties suggests.

[23] Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC Text with EEA relevance (2014) OJ L 86.

[24] Article 26 and Articles 28-37 of the Treaty on the Functioning of the European Union (TFEU)

[25] Duncan, p. 1027.

[26] Article 4 of TFEU

[27] Article 6 of TFEU

To illustrate the ambitions of the Union, I can quote from the most recent draft report on the shortage of medicines - how to deal with an emerging problem (2020/0000(INI)).

The European Parliament in the draft report in response to the current COVID-19 situation calls for the harmonization of prices to counter recurrent shortages:

Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment.[28]

Moreover, the European Parliament optimistically calls for health sovereignty as the goal for future investment strategies:

A genuine industrial strategy must be developed for the pharmaceutical sector to enable the European Union to regain its health sovereignty and invest in the cutting-edge research needed to make Europe the world leader in innovation and excellence in the health sector.[29]

2. The right to health and the right to health care

Terminologically, there are two rights to which one can broadly refer to when one speaks of the protection of individual and collective health: the right to health and the right to health care.

First of all, I would like to clarify their relationship and then elaborate on their normative content.

In the EU Charter, article 35 is named as the right to health care.

The right to health care is perceived usually as similar to the right to medical care. It is perceived as a narrower right. However, both the right to health and the right to health

[28] DRAFT REPORT of 30 April 2020 on the shortage of medicines - how to deal with an emerging problem (2020/0000(INI)), Committee on the Environment, Public Health and Food Safety, European Parliament, paragraph 13.

[29] Ibid, paragraph 14.

care are deeply intertwined. To understand the normative scope of the right to health care in the legal framework of the European Union, one must proportionately refer to the normative scope of the right to health because the right to health formed a conceptual basis for the constitution of the right to health care.

2.1 The right to health

The right to health is an older right, which was perceived as a part of the right to an adequate standard of living in article 25 of the Universal Declaration of Human Rights.[30] With the International Covenant on Economic, Social and Cultural Rights, the right to health gained further recognition. The ICESCR explicitly sets out the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The ICESCR listed a demonstrative, not exhaustive content of the right to health in a form of general principles to which States shall approach: "the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child also mentioned health as part of the right to an adequate standard of living; the improvement of all aspects of environmental and industrial hygiene; the prevention, treatment and control of epidemic, endemic, occupational and other diseases; the creation of conditions which would assure to all medical service and medical attention in the event of sickness."[31]

In the European context, the right to health was codified in the European Social Charter, article 11:

With a view to ensuring the effective exercise of the right to protection of health, the Parties undertake, either directly or in cooperation with public or private organisations, to take appropriate measures designed inter alia:

1. *to remove as far as possible the causes of ill-health;*
2. *to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health;*

[30] United Nations General Assembly Res 217 A (III) of 10 December 1948.

[31] United Nations General Assembly Res 2200A (XXI) of 16 December 1966.

3. *to prevent as far as possible epidemic, endemic and other diseases, as well as accidents*.[32]

Additionally, the right to medical assistance is codified in article 13 of the ESC stating that anyone who is without adequate resources needs to be provided with the care necessitated by the conditions of his or her sickness.[33]

The right to health is not a static concept. As we can see even from these two major human rights treaties, the content of the right to health differs. There are many factors that influence its actual content. Apart from the wording of a particular article, it is e.g. the financial sustainability of public health in a particular state related to pricing of medicinal products, new technologies in public health or generally the development of standards of public health.

The right to health remained for a long time a paper right, having a legal form in a number of human rights documents but not being actually enforced. Murphy identifies the HIV/AIDS pandemic as a turning point after which the right to health started to be taken seriously. Health rights litigation for the first time crucially contributed to the access to antiretroviral treatment.[34]

2.1.1 General Comment No. 14

To identify the normative scope of the right to health, I will refer to General Comment No. 14, which clarifies the normative scope and human rights obligations codified in the ICESCR in article 12 the Right to the Highest Attainable Standard of Health. GC No. 14 mentions the drafting history of the right to health and stresses that it shall not be reduced to the right to health care. The right to health shall be understood as a wider right encompassing a wide range of socio-economic factors that influence conditions in which people can lead a healthy life. The right to health also extends to the underlying

[32] Article 11, Council of Europe, European Social Charter (Revised), 3 May 1996, ETS 163.

[33] Ibid, article 13.

[34] T. Murphy, *Health and Human Rights (Human Rights Law in Perspective)*, Oxford, Hart Publishing, 2013, p. 39.

determinants of health, such as access to nutritionally adequate food, housing, access to safe and potable water and adequate sanitation, safe and healthy working conditions, and a healthy environment.

General Comment No. 14 clarifies that the right to health or the right to health care does not constitute the right to be healthy. Of course, good health cannot be ensured by a state. Rather the right to health should be understood as an impetus to the highest attainable standard of health, which is conditioned by the individual's biological and socio-economic preconditions and a state's available resources. The right to health refers to the right to the enjoyment of a wide range of services, goods such as medicinal products and facilities, which serve for the realization of the right to health.[35]

According to General Comment No. 14, the right to health has a very broad normative content. Apart from timely and appropriate health care, it also includes the underlying determinants of health, "such as access to safe and potable water and adequate sanitation, an adequate supply of safe food, nutrition and housing, healthy occupational and environmental conditions, and access to health-related education and information, including on sexual and reproductive health."[36]

The right to health takes into account also decision-making, when it necessitates the participation of the population in all health-related policymaking at the community, national and international levels.[37]

2.1.1.1 General Comment No. 14 identified 4 essential features of the right to health:

1. States need to ensure the availability of health care including "functioning public health and health-care facilities, goods and services, as well as programmes."[38]

[35] CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12), Adopted at the Twenty-second Session of the Committee on Economic, Social and Cultural Rights, on 11 August 2000.

[36] Ibid, paragraph 11.

[37] Ibid, paragraph 11.

[38] Ibid, paragraph 12, point a.

Again it is important to stress that the precise nature of the facilities, good and services depends on the state's developmental level;[39]

2. The second feature is the accessibility of health care. Access to health care needs to be provided maintaining non-discrimination, physical accessibility, economic accessibility, and information accessibility.[40] From the practical point of view, it means that health facilities and services including key determinants of health such as safe and potable water must be accessible to everyone, even to those who cannot afford to pay for them. This fully applies also to medicinal products. States have the obligation to secure their accessibility maintaining the principles stated above. The only acceptable limit is the overall financial capacity of the health system, which greatly varies from state to state;

3. The third feature is acceptability, which sets out ethical limits on health facilities, goods and services. States need to ensure that they are "respectful of medical ethics and culturally appropriate, i.e. respectful of the culture of individuals, minorities, peoples and communities, sensitive to gender and life-cycle requirements, as well as being designed to respect confidentiality and improve the health status of those concerned;"[41]

4. The fourth feature is the quality of health facilities, goods and services. Quality does not only concern, for instance, the quality of a medicinal product but a particular medicinal product needs to be scientifically proven and medically appropriate for the indicated use. Furthermore, quality applies also to medical personal who needs to be skilled enough to decide on the appropriateness of the medicinal product or to apply a particular medicinal product correctly. Again also underlying determinants of health such as safe and potable water are part of the

[39] Ibid, paragraph 12, point a.

[40] Ibid, paragraph 12, point b.

[41] Ibid, paragraph 12, point c.

scope of this provision such as safe and potable water needs to be understood as a part of quality.[42]

2.1.1.2 General Comment No. 14 specifies states' human rights obligations. General legal obligations are comprised of the following points:

1. States are obliged to take steps to the progressive realization of the right to health. The progressive realization means that "states parties have a specific and continuing obligation to move as expeditiously and effectively as possible towards the full realization of article 12."[43]

2. States are forbidden to take retrogressive measures unless there is no other alternative and they are appropriately justified by reference to the entirety of the rights codified in the ICESCR and the state party proved that it used the maximum of its available resources on the health system.[44]

3. Apart from the general human rights obligations to respect, protect and fulfill, the right to health also requires states parties—under the obligation to fulfill—to facilitate, provide and promote. The obligation to promote is in the context of the right to health and the work of WHO of special importance. State parties need to adopt appropriate legislative, administrative, budgetary, judicial, and other measures towards the full realization of the right to health. The obligation to respect necessitates state parties to not interfere directly or indirectly with the enjoyment of the right to health and the obligation to protect requires States to take measures that prevent third parties from interfering with article 12.[45]

[42] Ibid, paragraph 12, point d.

[43] Ibid, paragraph 31.

[44] Ibid, paragraph 32.

[45] Ibid, paragraph 33.

2.1.1.3 Specific legal obligations entail:

1. Under the obligation to respect states parties shall avoid discrimination against vulnerable groups such as asylum-seekers and illegal immigrants.[46] Likewise, States parties are obliged to refrain from denying, prohibiting or delaying access to medicinal products or health services.[47] This obligation is especially important in the context of trade policies. If a trade policy regularly results in a shortage of medicinal products, then the state is obliged to refrain from such a trade policy.

2. Under the obligation to protect state parties shall adopt legislation and other necessary measures to ensure equal access to health care and health-related services provided by third parties. States are obliged to ensure that health professionals and medical personnel follow ethical codes of conduct and meet the requirements of health education.[48]

General Comment No. 14 explicitly mentions economic threats to the right to health such as privatization of the health sector.[49] In the context of trade policies, it is clear that trade policies need to be implemented only if they do not constitute a threat to the availability, accessibility, acceptability and quality of medicinal products.

3. Under the obligation to fulfill state parties are obliged to give sufficient recognition to the right to health in the national political and legal systems, adopt the appropriate legislative framework and national health policy with a detailed plan for realizing the right to health.[50] In the context of trade policies, it follows that states are obliged to evaluate the consequences of trade policies on health systems and availability of a medicinal product, respectively, to count with their evaluation in national health policy. National health policy shall include all

[46] Ibid, paragraph 34.

[47] Ibid, paragraph 34.

[48] Ibid, paragraph 35.

[49] Ibid, paragraph 35.

[50] Ibid, paragraph 36.

determinants of health, especially those constituting a significant threat to availability, accessibility, acceptability or quality of medicinal products.

States need to ensure equal access for all to health care and to the underlying determinants of health.[51]

Access to the medicinal products needs to be guaranteed under the principle of non-discrimination. Practically, this applies also to the competition policy in the pharmaceutical market. States need to ensure that companies who sell medicinal products provide equal access to them.

4. Because the right to the health needs active approach of states to ensure its full realization, the obligation to fulfill includes three additional components:

    a. the obligation to facilitate, which requires states to take positive measures that enable and assist individuals and communities to enjoy the right to health;[52]

    b. the obligation to provide the right to health when individuals or a group are unable, for reasons out of their control, to realize that right themselves by the means of their willful disposal;[53]

    c. the obligation to promote the right to health necessitates states to take active steps in creating an environment where the health of the population can be maintained and restored.[54] This can be done by means of public debates, programs focused on prevention such as vaccination programs.

All of these obligations need to be fulfilled in accordance with cultural appropriateness of health care, favouring positive health results, disseminating appropriate information on

[51] Ibid, paragraph 36.

[52] Ibid, paragraph 37.

[53] Ibid, paragraph 37.

[54] Ibid, paragraph 37.

how to lead a healthy life and supporting people in making informed choices about their health.[55]

2.1.1.4 International obligations:

Already the Alma-Ata Declaration on primary health care stressed that the full realization of the right to health is impossible unless states cooperate internationally. The Alma-Ata Declaration proclaimed that the existing gross inequality in peoples' access to health is, first of all, rooted in the economic capabilities of various health systems.[56] This is especially evident when we compare the health systems in developed and developing countries but unacceptable differences in access to health care appear also within countries or among developed countries. We can see striking differences in the access to health care also among the member states of the EU. For example, in the range of medicinal products covered by health insurance or the availability of health professionals.[57] As the most serious and recent inequality in access to health care at the EU level are considered shortages of medicinal products.[58]

International human rights obligations consist of states' commitment to respect the enjoyment of the right to health in other countries, and to prevent violations by third parties in other countries, if they can influence these third parties by way of legal or political means, in accordance with the Charter of the United Nations and applicable international law.[59]

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[55] Ibid, paragraph 37.

[56] Article II, Alma-Ata Declaration, Report of the International Conference on Primary Health Care, Alma-Ata, 6-12 September 1978, in: World Health Organization, "Health for All" Series, No. 1, WHO, Geneva, 1978.

[57] See R. Baeten, S. Spasova, B. Vanhercke et al., *Inequalities in access to healthcare. A study of national policies 2018*, European Social Policy Network (ESPN), Brussels, European Commission, 2018, pp. 31-49.

[58] DRAFT REPORT of 30 April 2020 on the shortage of medicines - how to deal with an emerging problem (2020/0000(INI)), Committee on the Environment, Public Health and Food Safety, European Parliament

[59] CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12), paragraph 39.

International obligations require states to prevent third parties from causing shortages of medicinal products even if shortages occur in other countries. Therefore, if there are shortages of medicinal products, states are obliged to investigate its causes and take appropriate steps to prevent their occurrence because states are responsible to facilitate access to essential health facilities, goods and services in other countries, wherever possible.[60]

Similarly, states are obliged to pay attention that the right to health is realized through international agreements and international organizations. States parties should take actions to ensure that legal instruments do not adversely impact upon the right to health.[61]

In the context of a pandemic health crisis, international obligations of states are of crucial importance because states should refrain from imposing embargoes or similar measures restricting the supply of another state with adequate medicinal products and medical equipment.[62] However, as we can observe in the current COVID-19 pandemic crisis, there are many countries that disregard their obligations. As the Congressional Research Service observed: "As of May 1, at least 50 countries have taken at least 95 actions to impose export restrictions on medical goods, a category that includes general medical supplies."[63]

2.1.1.5 Core obligations:

The core obligations state minimum essential levels of each of the rights articulated in the ICESCR.

The core obligations with regards to the right to health entail:

[60] Ibid, paragraph 39.

[61] Ibid, paragraph 39.

[62] Ibid, paragraph 41.

[63] Congressional Research Service, 'Export Restrictions in Response to the COVID-19 Pandemic,' 15 May 2020 (accessed 18 June 2020).

1. the right of access to health facilities, goods and services on a non-discriminatory basis needs to be secured by states, especially for vulnerable or marginalized groups;

2. access to the underlying determinants of health needs to be secured such as minimum essential food which is nutritionally satisfactory and safe to eat, states need to ensure freedom from hunger to everyone;

3. access to basic shelter and housing, which satisfies minimum hygienic standards, sanitation, and an appropriate supply of safe and potable water;

4. essential drugs need to be secured and their list needs to be revised according to the WHO Action Programme on Essential Drugs;

5. equitable distribution of all health facilities, goods and services;

6. adoption and implementation of a national public health strategy and epidemiological actions plan, which addresses concrete challenges to the health of the whole population; the plan and the strategy needs to be periodically revised and the population of a particular say needs to have the right to participate on the establishment of the strategy and the plan.[64]

The ICESCR also specifies other comparable obligations, which relate to the core obligations.[65]

Apart from the normative content, which is identified in the obligations stated above, the ICESCR demonstratively lists violations.

[64] CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12), paragraph 43, points a-f.

[65] Ibid, paragraph 44.

2.1.1.6 Violations of the human rights obligation of article 12 of the ICESCR:

Most importantly, the ICESCR distinguished between the inability and the unwillingness of a State party to comply with its human rights obligations.[66]

Specifically to the right to health, the unwillingness is defined when a state does not use the maximum of its available resources for the realization of the right to health and therefore, commits a violation of its obligations under article 12.[67]

The inability is defined as a situation when a state uses all of its available resources on the full realization of the right to health but the limited amount of funding sets constraints on the overall capability of a health system. Then, a state needs to justify that it took every effort that could be reasonably demanded to use its resources to fulfill the obligations outlined above.[68]

However, states cannot justify its violation of the core obligations, which are non-derogable.[69]

It is important to note that as a violation of the right to health can be judged not only a direct action of a state but also a situation when a state does not sufficiently regulate other entities.[70] The other entities can be pharmaceutical companies, pharmaceutical distributors, etc.

Therefore, the ICESCR explicitly recognizes that violations can be caused by both actions of a state, *acts of commission* and *acts of omission*.[71]

As a violation of the right to health are recognized:

[66] Ibid, paragraph 47.

[67] Ibid, paragraph 47.

[68] Ibid, paragraph 47.

[69] Ibid, paragraph 47.

[70] Ibid, paragraph 48.

[71] Ibid, paragraph 48-49.

1. violations of the obligation to respect, namely, "the denial of access to health facilities, goods and services to particular individuals or groups as a result of de jure or de facto discrimination; the deliberate withholding or misrepresentation of information vital to health protection or treatment; the suspension of legislation or the adoption of laws or policies that interfere with the enjoyment of any of the components of the right to health; and the failure of the State to take into account its legal obligations regarding the right to health when entering into bilateral or multilateral agreements with other States, international organizations and other entities, such as multinational corporations;"[72]

2. violations of the obligation to protect, namely, "omissions as the failure to regulate the activities of individuals, groups or corporations so as to prevent them from violating the right to health of others; the failure to protect consumers and workers from practices detrimental to health, e.g. by employers and manufacturers of medicines or food; the failure to discourage production, marketing and consumption of tobacco, narcotics and other harmful substances; the failure to protect women against violence or to prosecute perpetrators; the failure to discourage the continued observance of harmful traditional medical or cultural practices; and the failure to enact or enforce laws to prevent the pollution of water, air and soil by extractive and manufacturing industries;"[73]

3. violations of the obligation to fulfill, namely, "the failure to adopt or implement a national health policy designed to ensure the right to health for everyone; insufficient expenditure or misallocation of public resources which results in the non-enjoyment of the right to health by individuals or groups, particularly the vulnerable or marginalized; the failure to monitor the realization of the right to health at the national level, for example by identifying the right to health indicators and benchmarks; the failure to take measures to reduce the inequitable distribution of health facilities, goods and services; the failure to adopt a gender-

[72] Ibid, paragraph 50.

[73] Ibid, paragraph 51.

sensitive approach to health; and the failure to reduce infant and maternal mortality rates."[74]

2.2 The legal framework of the European Union on health policymaking and the right to health care

2.2.1 The Treaty on the Functioning of the EU

Common safety concerns in public health matters for aspects stated in the Treaty on the Functioning of the EU belong to shared competence between the Union and the Member States.[75]

In addition to shared competence in common safety concerns, the Union has the competence to carry out actions to support, coordinate or supplement the actions of the Member States with regards to the protection and improvement of human health.[76]

The EU shall take into account requirements linked to the training and protection of human health in defining and implementing its policies and activities.[77]

These three articles, 4, 6 and 9 set out general principles and areas of competence for the Union's policymaking in public health.

The scope of the commitment of the European Union to protect health is more specifically codified in article 168 of TFEU:

1. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and

[74] Ibid, paragraph 52.

[75] Article 4 of TFEU

[76] Article 6 of TFEU

[77] Article 9 of TFEU

obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.

The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed.

3. The Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:

(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

(b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;

(c) measures setting high standards of quality and safety for medicinal products and devices for medical use.

5. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States.

6. The Council, on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article.

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 measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.[78]

From article 168 follows that the Union has the competence to take a number of actions to tackle policy challenges in public health but it shall always act complementary to national policies and respect responsibilities of the member states for health policymaking at a national level. The responsibilities of the Union are limited on the definition and implementation of its policies and actions. For example, the Union is responsible that the Internal market of the EU will contribute to a high level of human health protection. If it would turn out that the rules of the Internal market constitute a threat to the protection of

[78] Article 168 of TFEU.

human health, then the EU is responsible to take any action necessary and adopt a new regulatory framework, which ensures a higher level of human health protection.

2.2.2 The Charter of Fundamental Rights of the European Union

The European Union is acknowledged to be a duty-bearer *sui generis* of human rights obligations (as a part of shared competence together with member states) with regards to health rights by leading experts in health law.[79] The degree to which it bears human rights obligations needs to be always considered in relation to Union's supranational character and its competences. Specifically to the right to health care, we need to take into account that there is no Union's health care system. Rather, the Charter together with TFEU is a source of human rights obligations to which the Union is committed in legislative acts, policies, and actions of its institutions, bodies, offices, agencies, and in supervening Member States' implementation of Union's law.[80]

As already mentioned above, the right to health care is codified in article 35 of the Charter on Fundamental Rights.

Article 35 closely follows the wording of TFEU with regards to shared competence. From the perspective of the Union, it is responsible to ensure that its legislative acts, policies and activities will contribute to a high level of human health.

Member States are responsible for their implementation at the national level as well as for national laws and practices. Member states are responsible that everyone has the right to access to preventive health care, the right to benefit from medical treatment and other goals to achieve a high level of human health protection mentioned above in TFEU.

[79] For example, the chapter Health Rights and Human Rights in T. Hervey and J. V. McHale, *European Union Health Law: Themes and Implication*, United Kingdom, Cambridge University Press, 2015 or the chapter on article 35 in S. Peers,T. Hervey, T., Kenner, J. et al., *The EU Charter of Fundamental Rights: A Commentary*, United Kingdom, Bloomsbury Publishing, 2014.

[80] S. Peers , T. Hervey, J. Kenner et al., *The EU Charter of Fundamental Rights: A Commentary*, United Kingdom, Bloomsbury Publishing, 2014, pp. 951-952.

3. Trade-related challenges to the right to health care in the European Union

For example, if there is a shortage of medicines in the Member States as a result of the Union's trade policies on the Internal market, one can reasonably ask whether the European Union fulfills its human rights obligations which stem out from the articles mentioned above.

3.1 Parallel import and export of medicinal products

The first part of my thesis analysis the causal link between parallel import and export of medicinal products and increasing shortages of medicinal products as a result of the European Union's policies and whether it constitutes a violation of the article 35 of the Charter of Fundamental Rights of the European Union on the right to health care. Parallel imports and exports of medicinal products are conducted by companies with appropriate licenses to buy, sell and distribute medicinal products. Typically, the companies concerned with parallel trade buy medicinal products from member states with lower price levels of medicinal products and sell them to member states with higher price levels of medicinal products.

Parallel trade is believed to reduce the prices of medicinal products. Thus, improve the welfare of consumers and the functioning of health systems. However, what if this liberal economic logic is mistaken? Petit identifies parallel trade as a dogma of competition law because we do not have sufficient evidence to believe that it is as beneficial as theoretical economists think. According to Petit, the EU promotes an extremely sympathetic and protective legal regime, however, it lacks economic evidence supporting the approach of the Union. Petit elaborates on the downsides of parallel trade, which in case of luxurious good may not be so serious but in the case of availability of medicinal products may be crucial for the proper functioning of health systems. The problematic points are:

1. there is no undoubted theoretical or empirical evidence that parallel trade improves short-term consumer welfare;

2. parallel trade may harm long-term consumer welfare, through a detrimental effect on commercial and technological innovation;
3. parallel trade promotes speculation and other economic activities that reduce effective competition;
4. parallel trade may cause a range of collateral welfare-reducing effects on society at large. [81]

Why does the Union stick to parallel trade? Parallel trade is believed to make the competition more effective. Unjustified restrictions of it are generally seen as having an anti-competitive object. This view was held also by the Court of Justice in *GlaxoSmithKline*.[82] GlaxoSmithKline was found to violate Article 81(1) EC because it concluded an agreement with a wholesaler from Spain with a condition that the wholesaler shall not sell the medicinal products bought from GSK to the UK where the prices of medicinal products were significantly higher. This agreement was found to have an anti-competitive object. An anti-competitive object does not need to be proved only by the deprivation of final consumers of the advantages of effective competition in terms of supply or price, but also if it has negative effects on the structure of the market.[83]

The legal basis on the prohibition of restrictions of parallel trade is given in articles 101 and 102 of TFEU.

Article 101, paragraph 1, point a of TFEU states:

1. The following shall be prohibited as incompatible with the internal market: all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as

[81] N. Petit, 'Parallel Trade: econ-oclast thoughts on a dogma of EU competition law', in I. Govaere, R. Quick and M. Bronckers (eds.), *Trade and Competition Law in the EU and Beyond*, Cheltenham, Edward Elgar Publishing, 2011, pp 332-349.

[82] Court of Justice of the European Union, CJ, CJ, C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P. [2009], ECLI:EU:C:2009:610, *GlaxoSmithKline Services Unlimited v Commission and Others*, 6 October 2009, para. 66.

[83] Court of Justice of the European Union, CJ, CJ, C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P. [2009], ECLI:EU:C:2009:610, *GlaxoSmithKline Services Unlimited v Commission and Others*, 6 October 2009, para. 63.

their object or effect the prevention, restriction or distortion of competition within the internal market, and in particular those which:

(a) directly or indirectly fix purchase or selling prices or any other trading conditions;[84]

However, article 101 also states that the paragraph 1 shall not be applied if there are concerted practices that contribute *to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does not:*

(a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives;

(b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.[85]

Article 101 is trying to find a balance between effective competition and restrictions of it. The restrictions of effective competition are permissible only if they bring additional benefits such as improved availability of medicinal products or technological innovations benefitting consumers.

Article 102 of TFEU prohibits misuse of a dominant position within the internal market or in a substantial part of it. It explicitly forbids:

(a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;

(b) limiting production, markets or technical development to the prejudice of consumers;

(c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;

[84] Article 101 TFEU, paragraph 1, point a.

[85] Article 101 TFEU, paragraph 3, points a and b.

(d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.[86]

3.1.1 The legal framework of the European Union

Parallel trade is believed to reduce the prices of medicinal products. Thus, improve the welfare of consumers and the functioning of health systems. The paradigm behind the parallel trade comes from the mainstream liberal economic thought, which promotes competition as the most effective redistribution and pricing mechanism. This logic is behind the free movement of goods in article 34 of TFEU. Parallel imports and exports of medicinal products are compatible with the free movement of goods.

Article 34 of TFEU states:

Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States. [87]

Article 34 forms a legal basis for parallel import and export of medicinal products to be considered a lawful form of trade within the Internal Market of the EU.

Member States may, however, in certain cases restrict parallel trade, as long as the measures are justified, reasonable and proportionate to ensure a legitimate public interest. For example, to ensure an adequate and continuous supply of medicinal products to the population due to the present shortages of medicinal products.

These measures are justified in article 36 of TFEU:

The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or

[86] Article 102 TFEU, points a-d.

[87] Article 34 of TFEU

the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.[88]

The lack of appropriate and continued supplies of human medicinal products to pharmacies is a serious and growing problem that has occurred in recent years in a number of member states, namely Poland, Romania, Slovakia and Czechia and can gravely impact the treatment of patients. The Commission acknowledged that parallel trade of medicinal products may be one of the reasons for the occurrence of shortages of a number of medicinal products for human use.[89] It seems that Member States' restrictions of parallel trade according to article 36 of TFEU are ineffective as these shortages seem to be a side-effect of the Union's trade policies within the Internal market.[90]

If this is true, then it is the Union who has the responsibility to take actions and adopt legislation that would counter these "side-effects".

3.1.2 What are the unforeseen consequences of parallel trade?

3.1.2.1 The effects on the pricing of medicinal products in general

The main argument for adherents of parallel trade is that it decreases prices to a more effective level, which should be beneficial for the consumers. However, the evidence that

[88] Article 36 of TFEU

[89] The European Parliament adopted the resolution of 2 March 2017 on EU options for improving access to medicines (2016/2057(INI)) OJ C 263. This resolution was adopted on the grounds stated in the recital S "whereas certain essential medicines are not available in many Member States, which can lead to problems with regard to patient care; whereas a number of medicine shortages can occur either because of illegitimate business strategies, such as 'pay for delay' in the pharmaceutical sector, or political, manufacturing or distribution issues, or parallel trade; whereas Article 81 of Directive 2001/83/EC stipulates measures to prevent pharmaceutical shortages by means of a so-called public service obligation (PSO), which obligates manufacturers and distributors to safeguard supplies to national markets; whereas, in many cases, the PSO is not applied to manufacturers supplying the distributors, as indicated in a study commissioned by the Commission."

[90] N. Petit, 'Parallel Trade: econ-oclast thoughts on a dogma of EU competition law', in I. Govaere, R. Quick and M. Bronckers (eds.), Trade and Competition Law in the EU and Beyond, Cheltenham, Edward Elgar Publishing, 2011, pp 332-349.

this is true is not sufficient or even against this hypothesis.[91] From older studies, I can mention a study conducted by Patrizia Danzon in 1998, which came to an interesting explanation of why the economic logic behind parallel trade fails. Danzon concluded that parallel trade in medicinal products does not generate the normal efficiency gains from trade (presupposed by theoretical models) because countries achieve low pharmaceutical prices by directive aggressive regulation, not through improved efficiency.[92] It is policymakers who artificially set up prices of medicinal products (through regulations with the specific administrative procedure), not the market.

Therefore, from an idea that seems to be in line with liberal economic thought, we came to a counter-intuitive result, which is against liberal economic thought. This shall remind us of Frédéric Bastiat's famous text about intricacies of economics *That Which Is Seen, and That Which Is Not Seen*. However, what matters the most are the unseen consequences, which shall push a good economist or a good policymaker to change the initial—possibly driven by good intentions—idea. The unforeseen consequences, in this case, are an artificial price gap, unfair competition, corruption practices, and speculations on prices of medicines leading to shortages of medicinal products. The unforeseen consequences altogether significantly decrease the availability of health care.

Before I will elaborate on each of the unforeseen consequences, I need to comment on the studies, which shows contrary results of the parallel trade on prices. Some studies show that parallel trade resulted in a minor decrease in prices, roughly up to 10%. Furthermore, there is a third group of studies, which hardly detects a change in prices. I will turn back to the important observation made by Danzon. The explanation stated

[91] Petit quotes the results of a study conducted by LSE "*the hypothesis that pharmaceutical parallel trade stimulates price competition and drives prices down in destination (importing) countries over the long-term is rejected. There is also very little evidence lending support to the argument that parallel trade stimulates (price) competition among exporting and importing countries. Thus, the arbitrage hypothesis of price equalisation or price approximation is also rejected*" P. Kanavos, J. Costa-i-Font, S. Merkur and M. Gemmill, 'The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis', MA Special Research Paper, LSE Health and Social Care London School of Economics and Political Science, January 2004.

[92] P. Danzon, 'The Economics of Parallel Trade', *PharmacoEconomics*, vol. 13, no.3, 1998, 293-304.

above enables us to understand why there are studies that conclude with the beneficial effects of parallel trade.[93]

Not all of the price regulations by member states are artificial aggressive price regulation. In some cases, by a chance, price regulations can fit in the margin that the market can absorb. In such a situation, parallel trade can have beneficial effects in making the market more competitive.

3.1.2.2 Artificial price gaps

What interests me with regards to the topic of this thesis the most is if there is a causal link between shortages of medicinal products and the current parallel trade policies. Can parallel trade fail? How can an artificial price gap be created?

An artificial price gap is a gap in prices of the same products among countries, which is not generated by the market but it is the result of a regulation adopted by a state.

Different member states apply various approaches to price regulations. Some engage in reference pricing such as the Netherlands, Czechia, Greece, Italy.

Reference pricing is a regulation policy used by national authorities to regulate the prices of medicinal products. When a national authority wants to push a pharmaceutical company to lower the price of a medicinal product, which argument is the most convincing? Of course, the one that catches a pharmaceutical company to sell the medicinal product for a lower price in another country of the EU. Thus, some member states employed a policy, which takes an average price of a medicinal product from the three countries with the lowest price of medicinal products and pushes a pharmaceutical company to a reduction in the prices of medicinal products.

For example, Czechia is among countries, which apply an aggressive price regulation policy. Such a policy takes into account only prices of medicinal products in member

[93] U. Enemark, K.M. Pedersen and J.T. Sørensen, 'The economic impact of parallel import of pharmaceuticals', CAST - Centre for Applied Health Services Research and Technology Assessment, 2006, pp.1-72.

states of the EU with the lowest prices of medicinal products with no regard to the manufacturing costs of the medicinal products.

In Czechia, the average price of an original medicinal product containing ramiprilum 5mg, 100 tablets (widely used antihypertensive drug) is 5 EUR. In Germany, the same original medicinal product costs 25,62 EUR. Thus, in Czechia, the price is five times lower than in Germany.

Or even more peculiar comparison. Frequently used atorvastatinum was in the last years subjected to several significant regulations resulting in a very low price of an original medicinal product. The average price of atorvastatinum 20 mg, 100 tablets is 7 EUR. In Germany, the average price of the same medicinal product is 112,84 EUR.

If we try to compare the two countries by other indicators such as the average monthly disposable salary or costs of living, there is no justification for such a discrepancy in prices of medicinal products.

This leads me to a question: Who benefits from the gaps in prices and who does not?

It is clear that pharmaceutical companies do not benefit from the regulations of the prices of medicinal products. This fact corresponds to the general idea behind parallel trade, to decrease prices and lower prices for consumers. However, as shown in several studies mentioned above, the prices of medicinal products are often not decreasing, rather the discrepancy in prices enabled importers and exporters of medicinal products to gain additional profit.[94]

Thus, parallel trade created room for another entity to participate in the market and get profit from a price gap in the costs of medicinal products among various countries of the EU.[95]

[94] A. N. Varona and C. C. Candelario, 'The Pharmaceutical Sector and Parallel Trade', in P. Figueroa and A. Guerreroeu (eds.), *Law of Competition and Trade in the Pharmaceutical Sector*, Cheltenham, Edward Elgar Publishing, 2019, pp. 407-409.

[95] ibid pp. 407-409.

Petit suggests two more arguments against the mainstream approach to parallel trade. He claims that parallel trade may decrease in the short-term welfare of the consumers because it precludes suppliers from employing socially efficient price differentiation. Furthermore, Petit claims that parallel trade may also decrease the satisfaction of positional goods consumers.[96]

3.1.2.3 Price differentiation

Optimal pricing is one of the most intricate topics of economics. Price differentiation can be positive or negative.

Theoretically, price differentiation is positive if it is Pareto efficient. This means that resources are allocated in a situation when they cannot be reallocated to make one individual better off without making at least one individual worse off. Price differentiation is negative if it makes individuals worse off, either economically or socially.[97]

Price differentiation of medicinal products is even more complicated than in the cases of other goods. On one hand, pharmaceutical companies and pharmaceutical distributors need to act in accordance with the rules of the Internal market of the EU. On the other, hand health systems, regulations of the prices of medicinal products are in the competence of the member states. We need to bear in mind that the Union's member states are not a homogenous group. There is a huge difference in GDP among the member states and consequently also in the financial capability of their health systems.

Price differentiation is thus an important tool of how to balance the availability of medicinal products in countries with lower price levels. Pharmaceutical companies can employ diverse pricing strategies for markets, in which the ability to pay is more limited than in others.

[96] N. Petit, p. 333.

[97] W.D., Reisel and L.M. Sama, 'The Distribution of Life-Saving Pharmaceuticals: Viewing the Conflict Between Social Efficiency and Economic Efficiency Through a Social Contract Lens,' *Business and Society Review*, vol. 108, no.3, 2003, pp. 365-387.

However, once the market mechanism is disrupted by direct regulations of prices by policymakers, the consequences need to carefully evaluated. Price differentiation, which creates an artificial price gap opens the market for companies that have very little added value to an improvement of health care. On the contrary, when their functioning is unlimited, it leads to shortages of medicinal products. Companies that import and export medicinal products do not research new medicinal products, they do not develop new technologies.[98] They simple parasite on differences in prices, which are created artificially.

Bearing in mind that empirical studies outlined above are often contradictory[99] on the benefits of parallel trade, policymakers shall think what do they, in reality, cause by policies based on the uncritical belief in parallel trade.

Several scholars who are researching the effects of parallel trade observed an important pattern, which can be applied to different fields of parallel trade. If parallel trade destabilizes the profitability of a pharmaceutical company in the country with higher prices of medicinal products, then it is likely to induce a chain of reactions by that company. A pharmaceutical company may lower the quantities of medicinal products sold for a lower price and if even after this move it cannot maintain profitability, it will leave the market in a country with lower price levels unserved.[100] [101] [102]

Consequently, an uncritical approach to parallel trade and aggressive price regulations result in serious shortages of medicinal products. These shortages do not have a short-term character, rather they signify a systematic disbalance in pricing among member

[98] A. N. Varona and C. C. Candelario, pp. 410-412.

[99] Contradiction in empirical sutdies on prallel trade i salso mentioned by A. N. Varona and C. C. Candelario, p. 423-424.

[100] T. Valletti and S. Szymanski, 'Parallel Trade, International Exhaustion and Intellectual Property Rights: A Welfare Analysis', *Journal of Industrial Economics*, Vol. 54, No. 4, 2006, pp. 499-526.

[101] F. Mueller-Langer, 'Does parallel trade freedom harm consumers in small markets?', *Croatian Economic Survey*, Vol. 1, No. 11,15 April 2009, pp. 11-41.

[102] G. M. Grossman and E. L.-C. Lai, 'Parallel Imports and Price Controls', *RAND Journal of Economics*, Vol. 39, No. 2, 2008, pp. 378–402.

states' markets. Furthermore, artificial price gaps can shift the market powers in a favourable direction for companies with very little added value. This leads to a chain of side-effects.[103] Pharmaceutical companies that have high added value because they are the ones who conduct research, develop innovative technologies will face several economic strains because their profit will be absorbed by parallel importers and exporters. Pharmaceutical companies will have to lower their budgets on research and innovations, they will have to optimize their human resources, which will lead to job losses, etc.

After all, the capability of health systems in countries with a strong emphasis on parallel export and price regulations will decrease rather than increase (which was the initial aim of parallel trade).

This leads me to a provisionary conclusion that price differentiation, which corresponds to long-term differences in price levels among member states is beneficial and shall not be eliminated by parallel trade. Especially, if it is employed as a result of the market competitors. However, price differentiation can be also caused artificially by aggressive regulations of prices. Then, it shifts profit from companies with higher added value to companies with lower added value and leads to a chain of negative side-effects, which in the end lead to shortages of medicinal products and decrease the capability of health systems in countries from which the medicinal products are exported.

3.1.2.4 Shortages of medicinal products

The shortages of medicinal products are a serious problem at the EU level, which lasts already for several years and according to the recent reports is still growing.[104] The COVID-19 pandemic crisis only signified the current unpleasant situation. Some of the frequently used medicinal products are in a number of member states often unavailable.

The draft report of the ENVI Committee of the European Parliament explicitly criticized untransparent distribution chains. It "recommends the introduction of centralized

[103] N. Petit, p. 335.

[104] DRAFT REPORT of 30 April 2020 on the shortage of medicines - how to deal with an emerging problem (2020/0000(INI)), Committee on the Environment, Public Health and Food Safety, European Parliament.

management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply."[105]

On one hand, the health systems in member states are increasing their financial capabilities. On the other hand, they face recurrent shortages of very important widely used medicinal products. How is this possible?

The artificial price gaps create a significant problem for pharmaceutical companies. If pharmaceutical companies produce medicinal products and sell them with lower gain or in some cases even under the production costs to the countries, which aggressively regulate prices of medicinal products, then they risk that these medicinal products will be exported to the countries, in which pharmaceutical companies are selling these medicinal products with a higher gain.

Parallel trade has a negative effect on the availability of medicinal products in countries, which apply strict regulations based on the average prices of medicinal products in countries with the lowest prices of medicinal products.

Pharmaceutical companies are trying to limit the number of medicinal products sold to the countries, which are the biggest regulators of the prices of medicinal products to minimize the loss if the medicinal products are sold under their production costs or to protect their share in the markets where pharmaceutical companies sell with a higher margin. Therefore, restrictions on the number of medicinal products shall effectively prevent re-exporting companies from substituting pharmaceutical companies in the countries where a particular medicinal product can be sold at a higher price.

The situation got so far that the ENVI Committee of the EP in its draft report especially proposes to call "on the Commission and the Member States to adopt a joint definition of 'medicines of strategic importance for health care' and of 'criticality', emphasizing the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; call for a European regulatory authority to be designated to carry

[105]Ibid paragraph 12.

out the task of setting quotas for the allocation of medicines from that reserve to the Member State."[106]

However, the European Parliament does not seem to acknowledge the root cause of the current situation. In line with Petit and Danzon, I claim that unprecedented and uncritical support of parallel trade as an exclusively beneficial practice led the policymakers astray. The parallel trade of medicinal products in the current form has a very serious long-term strain resulting in shortages of medicinal products.

3.1.2.5 Parallel Trade harms the Long-Term Welfare of Consumers, through a Detrimental Effect on Commercial and Technological Innovation

The profitability of companies with high added value is an important marker of future spendings on future research and development. If the profitability decreases under a certain threshold, one of the first areas where the reduction in costs is expected, apart from advertising, are long-term investments into an uncertain future.[107] Therefore, parallel trade may lower long-term consumer welfare if it lowers investments of the companies with high added value in research and development.

Whether parallel trade has these effects on a long-term scale or not depends on the differences between the prices and size of the import and export market. From recent studies, we can conclude that parallel trade is likely to have these consequences if the differences are higher. Thus, if some member states apply aggressive price regulations and others do not, it will likely have a detrimental effect on research and technological innovations.[108]

[106] DRAFT REPORT of 30 April 2020 on the shortage of medicines - how to deal with an emerging problem (2020/0000(INI)), Committee on the Environment, Public Health and Food Safety, European Parliament, paragraph 15.

[107] C. Li and K.E. Maskus, 'The impact of parallel imports on investments in cost-reducing research and development', *Journal of International Economics*, Vol. 68, No.2, 2006 pp.443-45.

[108] M., Reisinger, L. Saurí, and H. Zenger, 'Parallel imports, price controls, and Innovation', *Journal of Health Economics*, Vol. 66, 2019, pp. 163-179.

3.1.2.6 The legality of parallel trade: grey pharmacies and illegal distribution of medicinal products

Some pharmacies on the pharmaceutical market function only as pseudo-pharmacies when their primary purpose is not to provide pharmaceutical care but to pull out medicinal products for parallel import and export from the market in a particular Member State. These pharmacies have secret agreements with distributors. I have collected evidence that the biggest distributor in Europe, the PHOENIX group created a cartel in the pharmaceutical market in Czechia, through which it influences the access to medicinal products in shortages. These medicinal products are often of interest to parallel trade. Through the ordering platform and secret button called reservations, which is available only to some pharmacies, the PHOENIX group provides unequal access to medicinal products. Therefore, the PHOENIX group discriminates ordinary pharmacies through its online platform, on which pharmacies place orders.

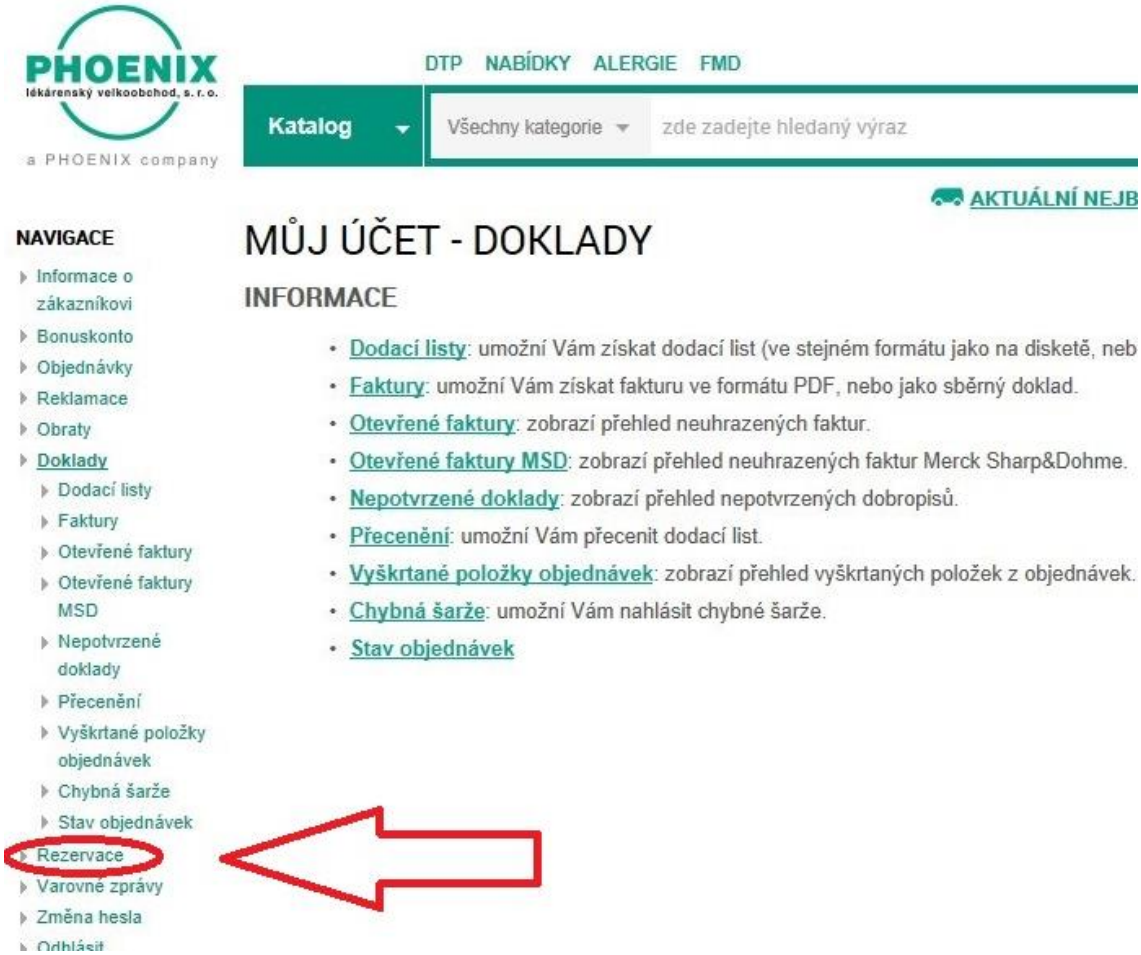
The reservation button is available only for a close number of pharmacies. When a medicinal product, which is in shortage arrives on the market, ordinary pharmacies do not have any chance to order it. This product is distributed only to pharmacies, which have "VIP access". Either they are pharmacies owned by the distributor such as pharmacy brand BENU.[109] Or they are pharmacies owned by companies that have secret agreements with the distributor to gain privilege access in exchange for high turnover with this distributor. To the pharmacies with "VIP access", the distributor provides an unfair competitive advantage.

This can be illustrated in the following screenshots, which were taken in two different pharmacies in Czechia at the same time. They both display the ordering system of the PHOENIX group, the biggest distributor of medicinal products in Europe. Pharmacy A is a pharmacy with "VIP access" and pharmacy B is a regular pharmacy.

[109] A real recipe for success. https://www.phoenixgroup.eu/en/press/latest/stories/a-real-recipe-for-success

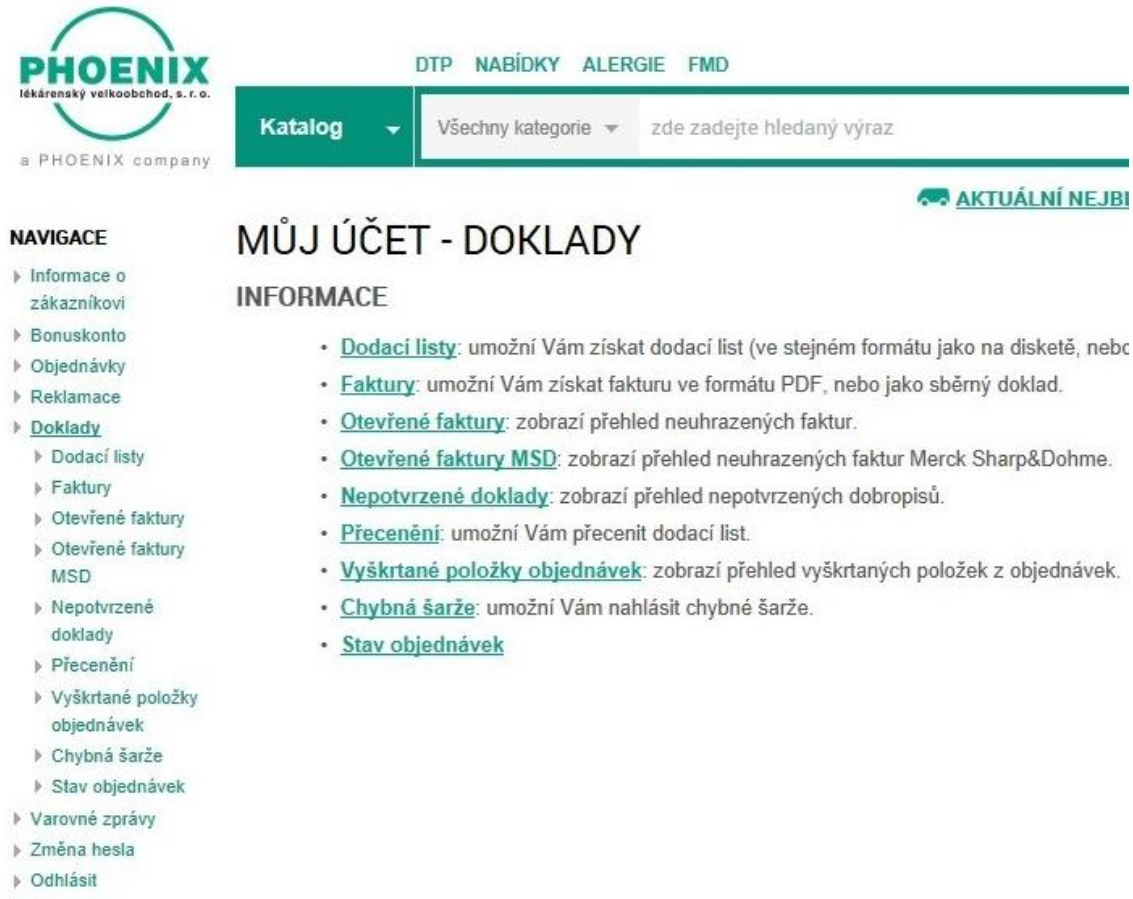
Pharmacy A is a privileged pharmacy, which has in the menu on the left a button called reservations (rezervace). Through this button, it can access medicinal products, which are not visible for regular pharmacies.

Figure 1: *Screenshot no. 1, pharmacy A reservations*



Pharmacy B is a regular pharmacy, which does not have access to reservations. The button reservations (rezervace) is missing in the ordering system. Regular pharmacies do not even know that something like reservations exists because the distributor hides this information from them. When a regular pharmacy asks about the availability of a medicinal product, which is interesting to parallel trade or is on a shortage list (or both), the distributor replies that the medicinal product is unavailable. In such cases, the distributor distributes these medicinal products only to pharmacies with "VIP access".

Figure 2: *Screenshot no. 2, pharmacy B reservations*



The claim stated above can be also demonstrated on examples with particular medicinal products. For example, on Flixotide 125 mcg inhaler.

Pharmacy A can see this product visible for a reservation.

Figure 3: *Screenshot no. 3, pharmacy A reservations*

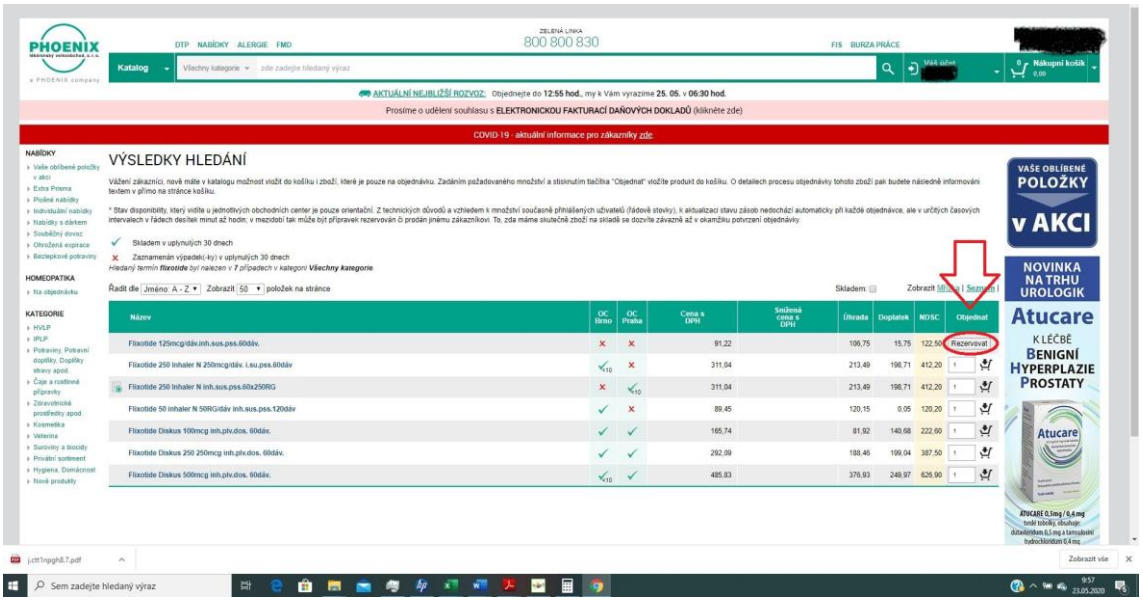


Figure 4: *Screenshot no. 3, pharmacy A reservations (zoomed)*

Pharmacy B cannot see Flixotide 125 mcg inhaler available. The button reservations is missing.

Figure 5: *Screenshot no. 4, pharmacy B reservations*

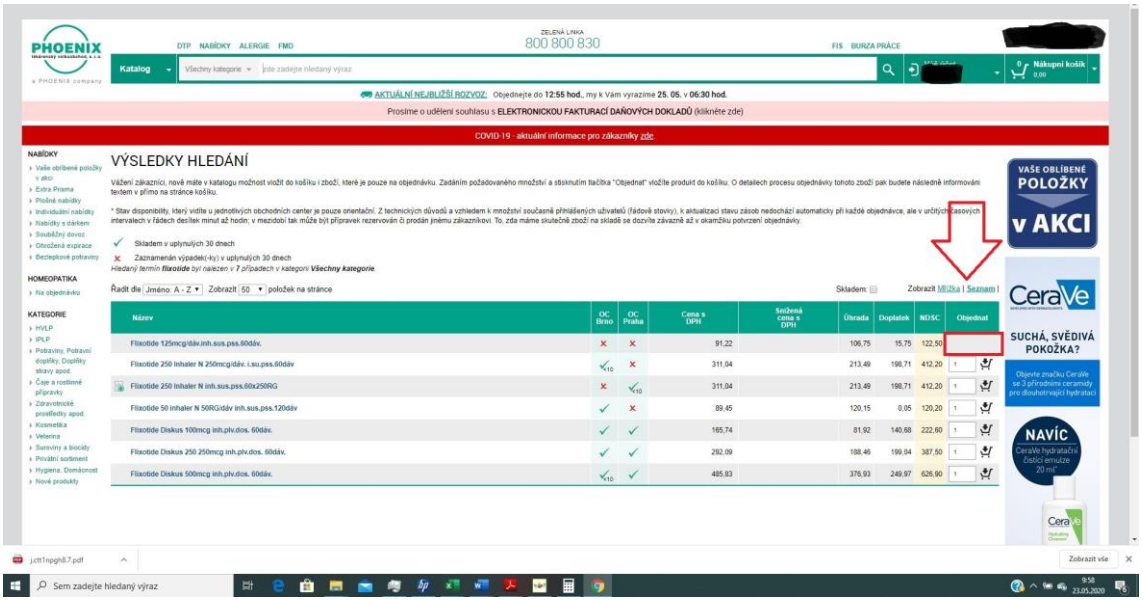


Figure 6: *Screenshot no. 4, pharmacy B reservations (zoomed)*

After the medicinal product arrives in the market, the distributor continues to hide its availability for regular pharmacies. This can be demonstrated on the example of Nutridrink 5+1 por.sol. 6x200ml, which has the status of a medicinal product and often is on a shortage list. Pharmacy A can order it.

Figure 7: *Screenshot no. 5, pharmacy A Nutridrink*

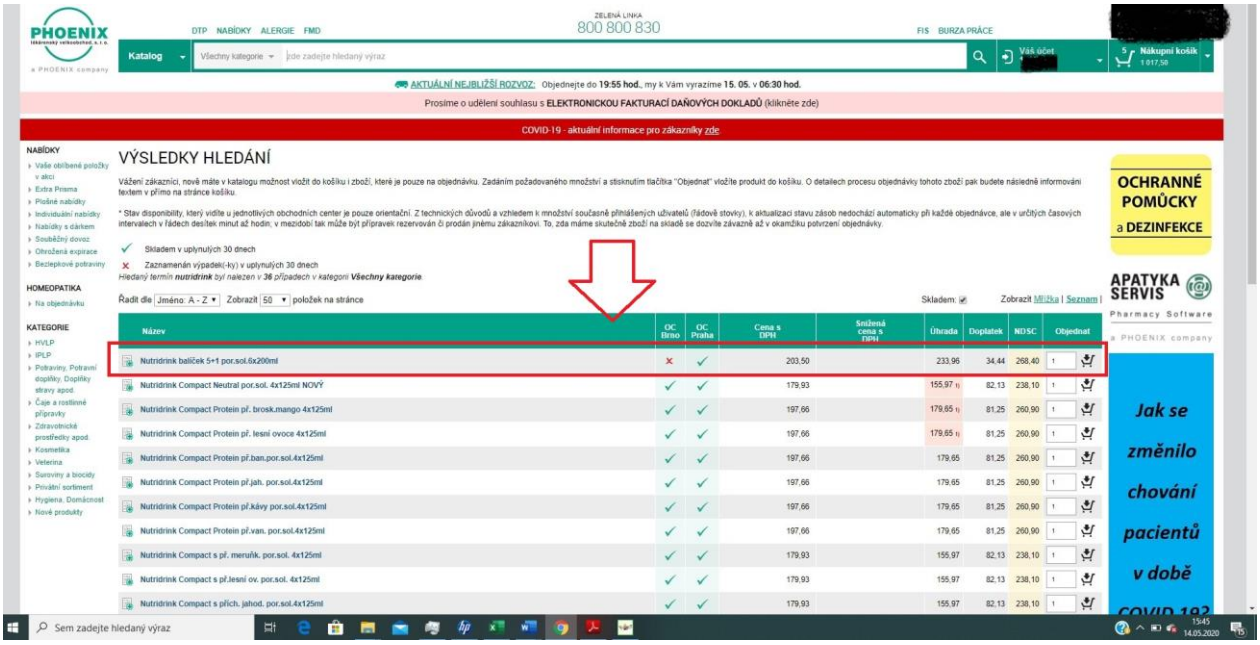
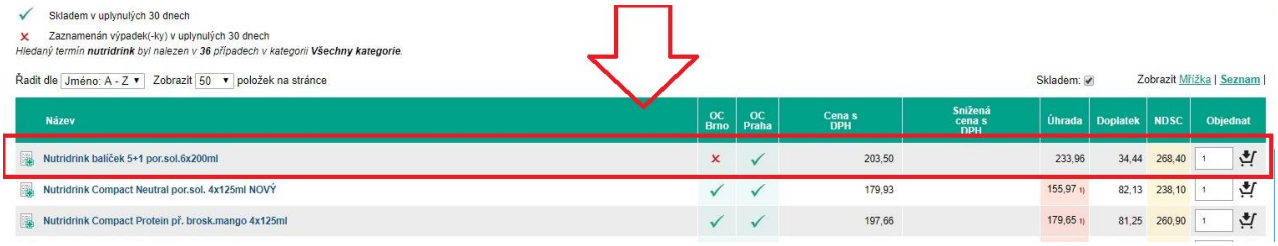


Figure 8: *Screenshot no. 5, pharmacy A Nutridrink (zoomed)*



Pharmacy B cannot see Nutridrink 5+1 por.sol. 6x200ml available. This medicinal product is simply missing in the ordering platform, although the screenshots are taken at the same time.

Figure 9: *Screenshot no. 6, pharmacy B Nutridrink*

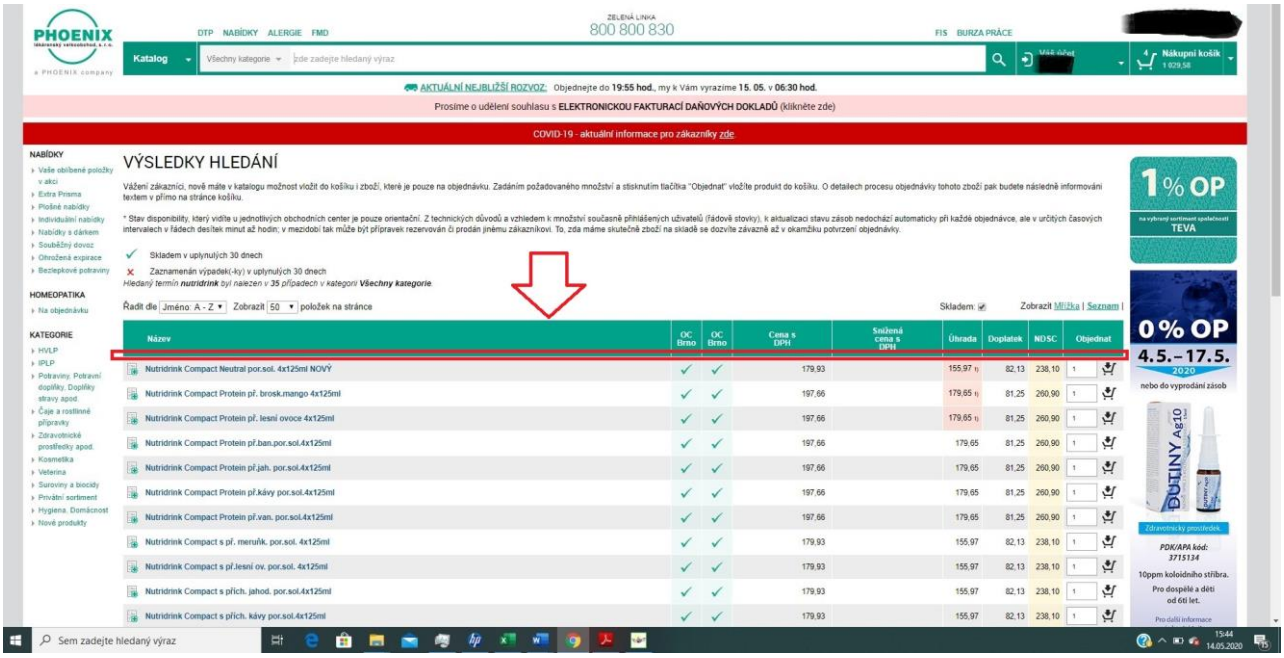


Figure 10: *Screenshot no. 6, pharmacy B Nutridrink (zoomed)*

In the context of the COVID-19 pandemic crisis, the distributor also limited access to important medicinal products including protective masks. This time, the distributor used different technical approaches to restrict certain pharmacies from ordering these products. The distributor let face masks to appear visible in the ordering system but blocked regular pharmacies (pharmacy B) from ordering them.

Pharmacy B asked for 5 packages of face masks that appeared to be available in the stock of the distributor. However, the ordering platform blocks the pharmacy from ordering the face masks with a note “the product is unavailable” (framed in red).

Figure 11: *Screenshot no. 7, pharmacy B face masks*

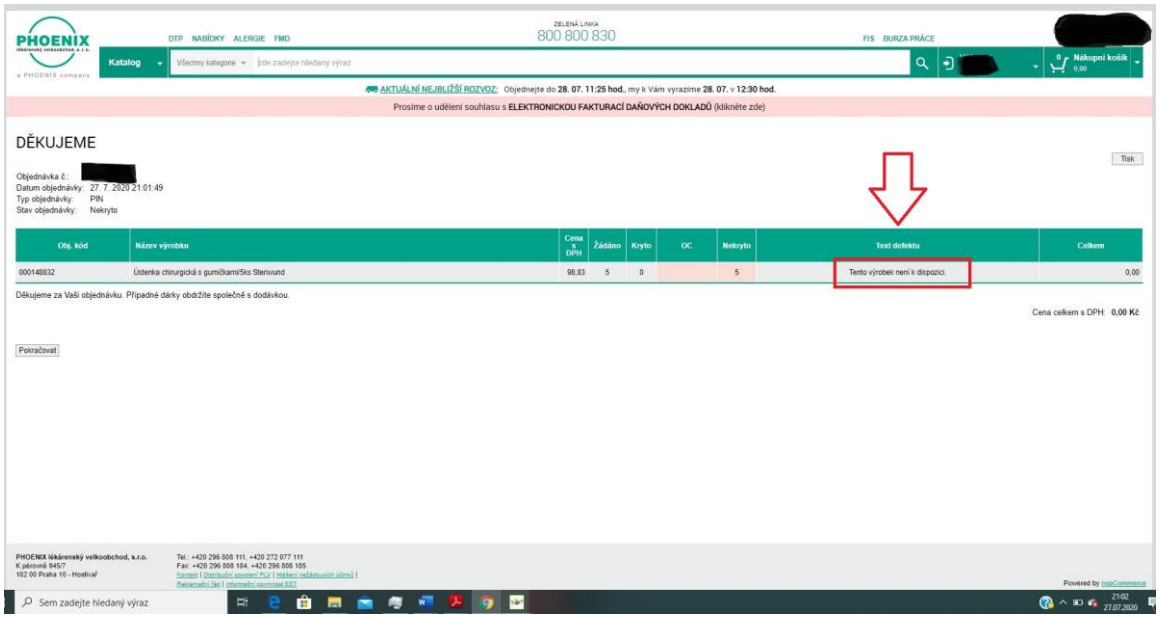
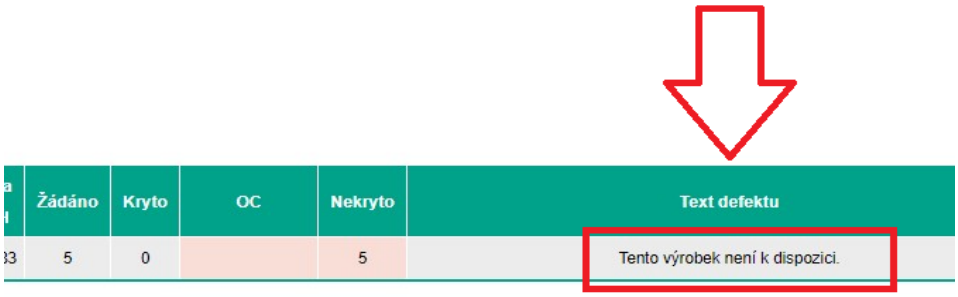


Figure 12: *Screenshot no. 7, pharmacy B face masks (zoomed)*



Furthermore, some of the pharmacies, which have "VIP access" to medicinal products granted by the PHOENIX group, participate in an illegal form of parallel trade.

Only pharmaceutical distributors can sell medicinal products from the member state with a lower price of the medicinal product to the member state with a higher price of the medicinal product. Pharmacies cannot distribute medicinal products across borders. At the same time, pharmaceutical distributors such as the PHOENIX group cannot sell the medicinal products only to the countries with higher price levels and leave the countries with lower price levels in a total shortage. Pharmaceutical companies in cooperation with national drug authorities set out the consumption of medicinal products for a particular country. Based on consumption data, pharmaceutical companies allocate a certain amount of medicinal products, which the distributor is obliged to distribute in the market of a particular member state. Because the pharmaceutical distributor is obliged to deliver a certain amount of medicinal products to a particular country, it cannot export them directly.

Companies involved in parallel trade came up with an illegal solution on how to overcome export restrictions. Because pharmaceutical distributors do not want to be traceable behind certain forms of parallel trade, they use pharmacies with "VIP access" to buy the medicinal products as if they should be used for the sale in the pharmacy.

Thus, it appears that the pharmaceutical distributor delivered the medicinal product in the country, for which it was allocated.

However, these pharmacies do not list the receipt of these products in the pharmaceutical software[110] but they sell them directly to a different pharmaceutical distributor, in the case that I investigated, it was Merkur Pharma, s.r.o. This distributor is used only for the export

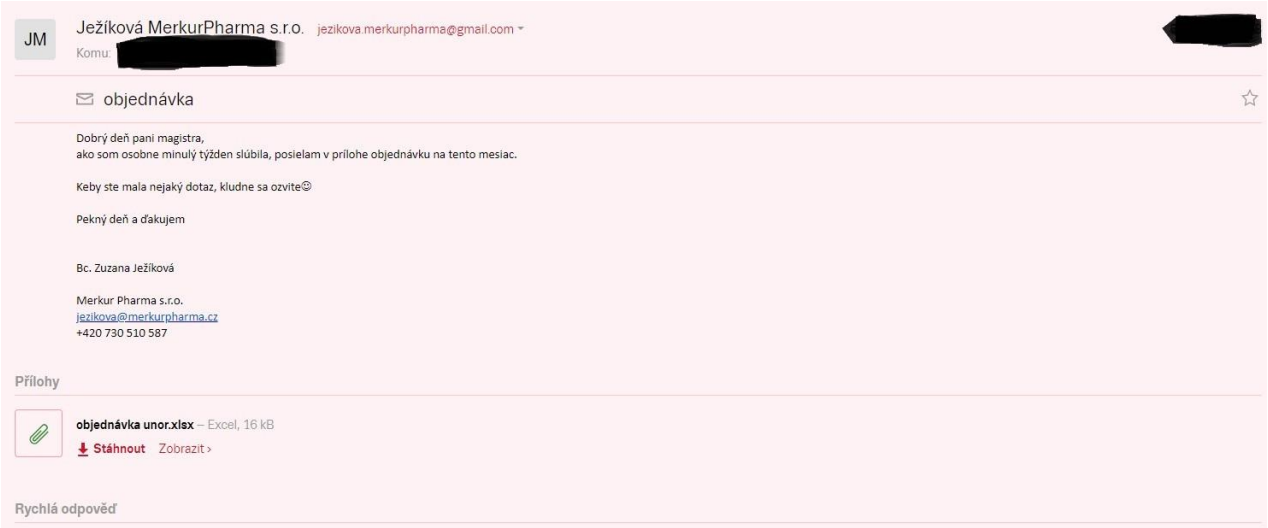
[110] To list that the medicinal product arrived is a standard legal procedure in the Union's member states. This obligation is explicitly stated in the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311. For example, according to Czech law, it is also codified in the law on medicinal products (§ 77 odst. 3 zákona č. 378/2007 Sb., o léčivech). It says that every reception of a medicinal product needs to be documented. The documentation should allow to follow the path of the medicinal product. Furthermore, it should allow to verify the amount and identification of the medicinal product (expiration date and the batch).

of these medicinal products to the member states with a higher price level of the medicinal product.

Pharmacies are according to the Czech law prohibited to sell products to the distributor for export.[111] Only pharmaceutical distributors can distribute medicinal products. However, some pharmacies act only as pseudo-pharmacies. To provide pharmaceutical care is only a cloak for them. Their actual business lies in buying medicinal products for export.

Screenshot no. 8 captures an email from Merkur Pharma s.r.o. containing an offer to a pharmacy to buy medicinal products from the distributor and then sell them to the Merkur Pharma without listing their reception. In the attachments is an Excel sheet, which contains medicinal products, in which exporters are interested in February 2020.

Figure 13: *Screenshot no. 8 Merkur Pharma, s.r.o. email*



[111] Medicinal products can be distributed only by pharmaceutical distributors with appropriate licence issued by the national drug authority. In Czech law, it is codified in paragraph 3 of article 75 of the law on medicinal products (§ 75 odst. 3 zákona o léčivech).

Transcription:

Subject: Order

Dear Ms. magister,

As I promised in person during the last week, I send the order for this month.

If you would have any questions, do not hesitate to contact me ☺

Have a nice day and thank you

Bc. Zuzana Ježíková

Merkur Pharma s.r.o.

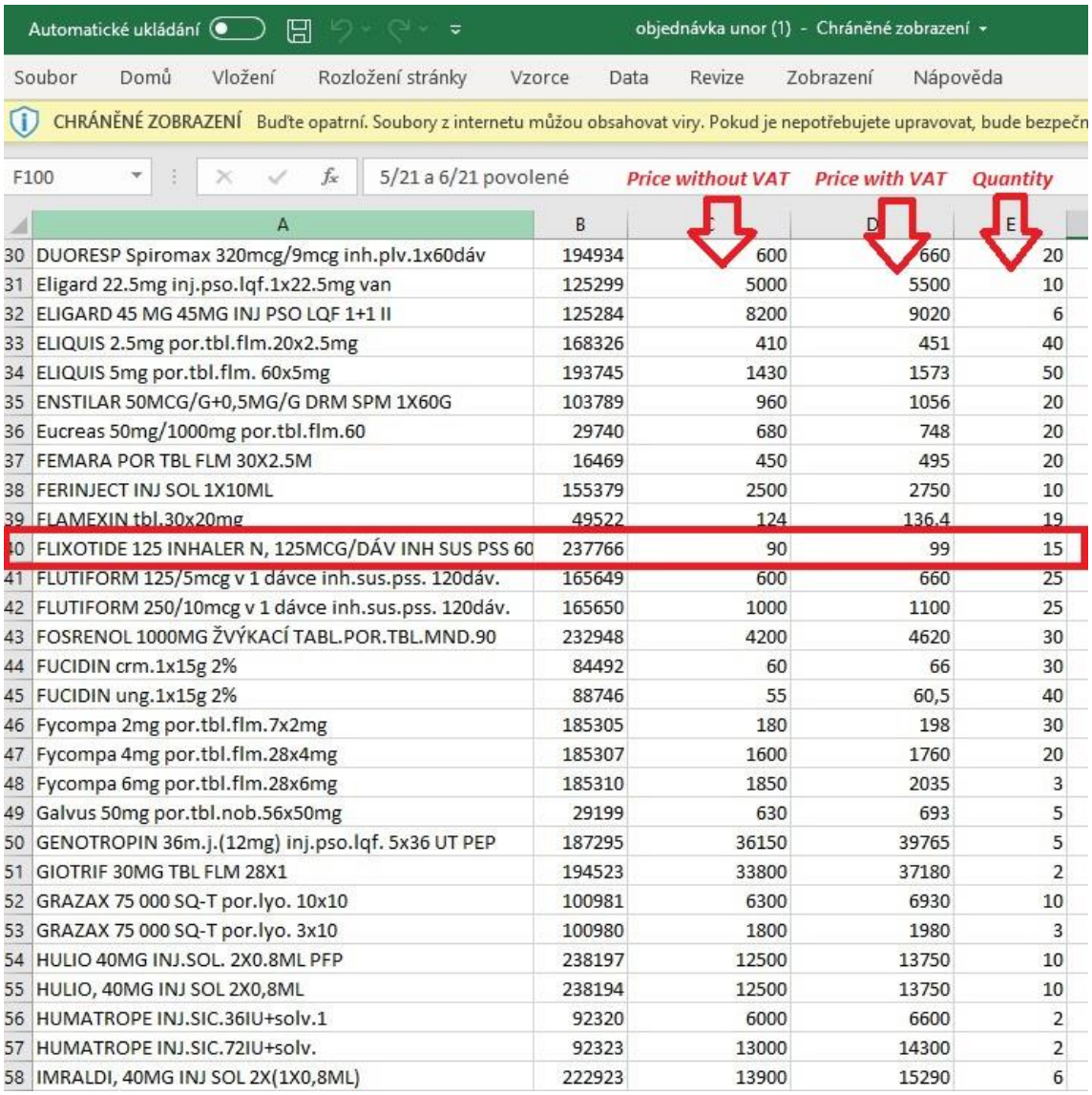
jezikova@merkurpharma.cz

+420 730 510 587

Attachment: Order for February

The excel sheet in the attachment contains 130 medicinal products and is included in the annex of the thesis. The excel sheet includes also Flixotide 125 mcg inhaler, which was shown unavailable to a regular pharmacy in a screenshot no. 4. The excel sheet also shows prices and quantity demanded after pharmacies to buy from the distributor.

Figure 14: *Screenshot no. 9 Merkur Pharma's list of medicinal products for export with prices February 2020*



	A	B	C	D	E
30	DUORESP Spiromax 320mcg/9mcg inh.plv.1x60dáv	194934	600	660	20
31	Eligard 22.5mg inj.pso.lqf.1x22.5mg van	125299	5000	5500	10
32	ELIGARD 45 MG 45MG INJ PSO LQF 1+1 II	125284	8200	9020	6
33	ELIQUIS 2.5mg por.tbl.flm.20x2.5mg	168326	410	451	40
34	ELIQUIS 5mg por.tbl.flm. 60x5mg	193745	1430	1573	50
35	ENSTILAR 50MCG/G+0,5MG/G DRM SPM 1X60G	103789	960	1056	20
36	Eucreas 50mg/1000mg por.tbl.flm.60	29740	680	748	20
37	FEMARA POR TBL FLM 30X2.5M	16469	450	495	20
38	FERINJECT INJ SOL 1X10ML	155379	2500	2750	10
39	FLAMEXIN tbl.30x20mg	49522	124	136,4	19
40	FLIXOTIDE 125 INHALER N, 125MCG/DÁV INH SUS PSS 60	237766	90	99	15
41	FLUTIFORM 125/5mcg v 1 dávce inh.sus.pss. 120dáv.	165649	600	660	25
42	FLUTIFORM 250/10mcg v 1 dávce inh.sus.pss. 120dáv.	165650	1000	1100	25
43	FOSRENOL 1000MG ŽVÝKACÍ TABL.POR.TBL.MND.90	232948	4200	4620	30
44	FUCIDIN crm.1x15g 2%	84492	60	66	30
45	FUCIDIN ung.1x15g 2%	88746	55	60,5	40
46	Fycompa 2mg por.tbl.flm.7x2mg	185305	180	198	30
47	Fycompa 4mg por.tbl.flm.28x4mg	185307	1600	1760	20
48	Fycompa 6mg por.tbl.flm.28x6mg	185310	1850	2035	3
49	Galvus 50mg por.tbl.nob.56x50mg	29199	630	693	5
50	GENOTROPIN 36m.j.(12mg) inj.pso.lqf. 5x36 UT PEP	187295	36150	39765	5
51	GIOTRIF 30MG TBL FLM 28X1	194523	33800	37180	2
52	GRAZAX 75 000 SQ-T por.lyo. 10x10	100981	6300	6930	10
53	GRAZAX 75 000 SQ-T por.lyo. 3x10	100980	1800	1980	3
54	HULIO 40MG INJ.SOL. 2X0.8ML PFP	238197	12500	13750	10
55	HULIO, 40MG INJ SOL 2X0,8ML	238194	12500	13750	10
56	HUMATROPE INJ.SIC.36IU+solv.1	92320	6000	6600	2
57	HUMATROPE INJ.SIC.72IU+solv.	92323	13000	14300	2
58	IMRALDI, 40MG INJ SOL 2X(1X0,8ML)	222923	13900	15290	6

3.1.2.7 Who benefits from the parallel import/export of medicinal products?

As outlined in the studies discussed above, the empirical evidence is ambiguous on the benefits of parallel trade for consumers. If the positive scenario prevails, consumers may expect a slight decrease in prices. However, it may also turn out, especially when the prices are overregulated that parallel trade will make them worse off. There is a higher probability of shortages or even increasing the price of a medicinal product.

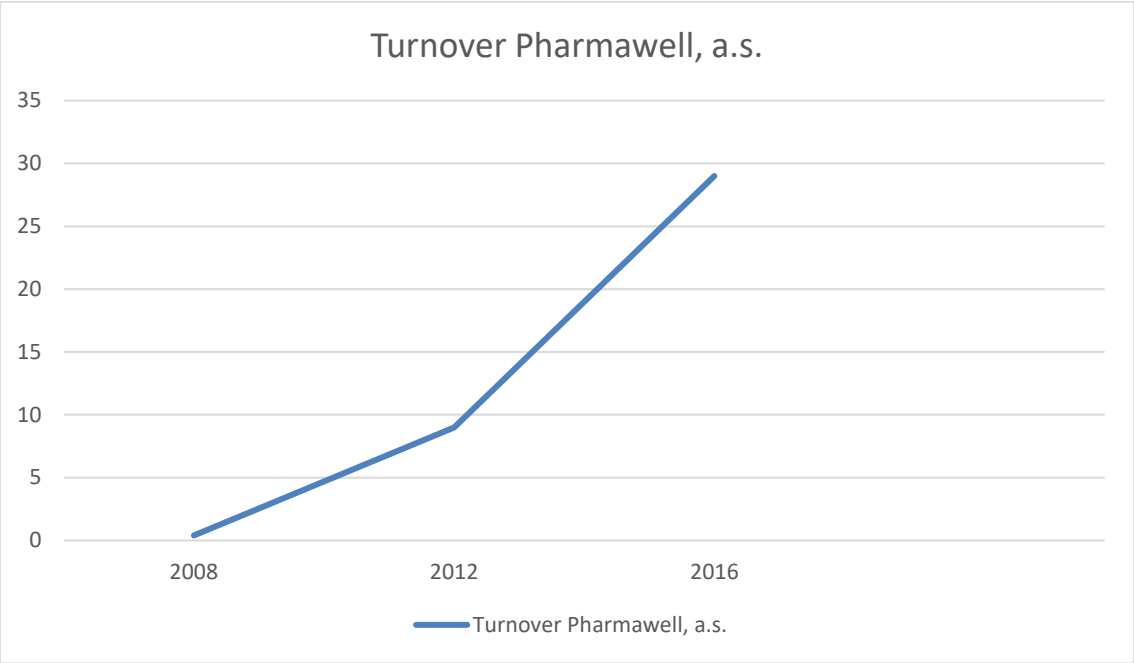
The margin, which is created by the differences in prices of an overregulated medicinal product in a country with lower price levels and a medicinal product in a country with higher price levels stays with the companies engaged in parallel trade.

To demonstrate this claim, I examined another parallel exporter from Czechia.

Pharmawell a.s. is a distributor of medicinal products with orientation on parallel trade similar to Merkur Pharma. Pharmawell, a.s. is owned and personally linked to the owners and management of a brand of pharmacies called "Chytrá Lékárna" (Clever Pharmacy). Through the chain of "clever pharmacies," it buys out medicinal products from the pharmaceutical market in Czechia. I have analyzed the data on the turnover of Pharmawell, a.s. available from public sources in the years 2008-2016. The turnover of Pharmawell, a.s. increased since 2008 from 0,4 mil. EUR to almost 30 mil. EUR in 2016.[112] Thus, it came to be one of the major players in the parallel trade of medicinal products in Czechia.

[112] Public Business Register, (Veřejný rejstřík a sbírka listin © 2012-2015 Ministerstvo spravedlnosti České republiky) (accessed 20 March 2020)

Chart 1: *Turnover Pharmawell, a.s. 2008-2016 in mil. EUR*



However, Pharmawell, a.s. uses a strategy, which is based on pseudo-pharmacies. Under the brand of clever pharmacies, it buys medicinal products supposedly for patients in Czechia and then sells them to Pharmawell, a.s., which then transports them to countries with higher price levels of medicinal products. This is only another example of illegal conduct described in the paragraphs above.

According to the law on medicinal products, pharmacies shall not be involved in the distribution of medicinal products. Nevertheless, this is exactly what happens, although it has a cloak of legal conduct because the brand of pharmacies (strategically linked to Pharmawell) is using an exception the law on medicinal products for returning the unused medicinal products to a different distributor.

For example, it buys a medicinal product from PHOENIX and then claims that the medicinal product is unnecessary stock, for which the law has an exception that unsued stock can be returned to the distributor. However, it does not return it to PHOENIX but it returns it to Pharmawell, a.s. Needless to say that these medicinal products are not unnecessary stock but they are intentionally bought for export.

3.1.2.8 The destruction of pharmaceutical markets in member states of the European Union with lower price levels

Apart from shortages of medicinal products in member states with lower price levels, parallel trade is a source of another very serious problem, which effectively destructs competition in the pharmaceutical markets of member states with lower price levels.

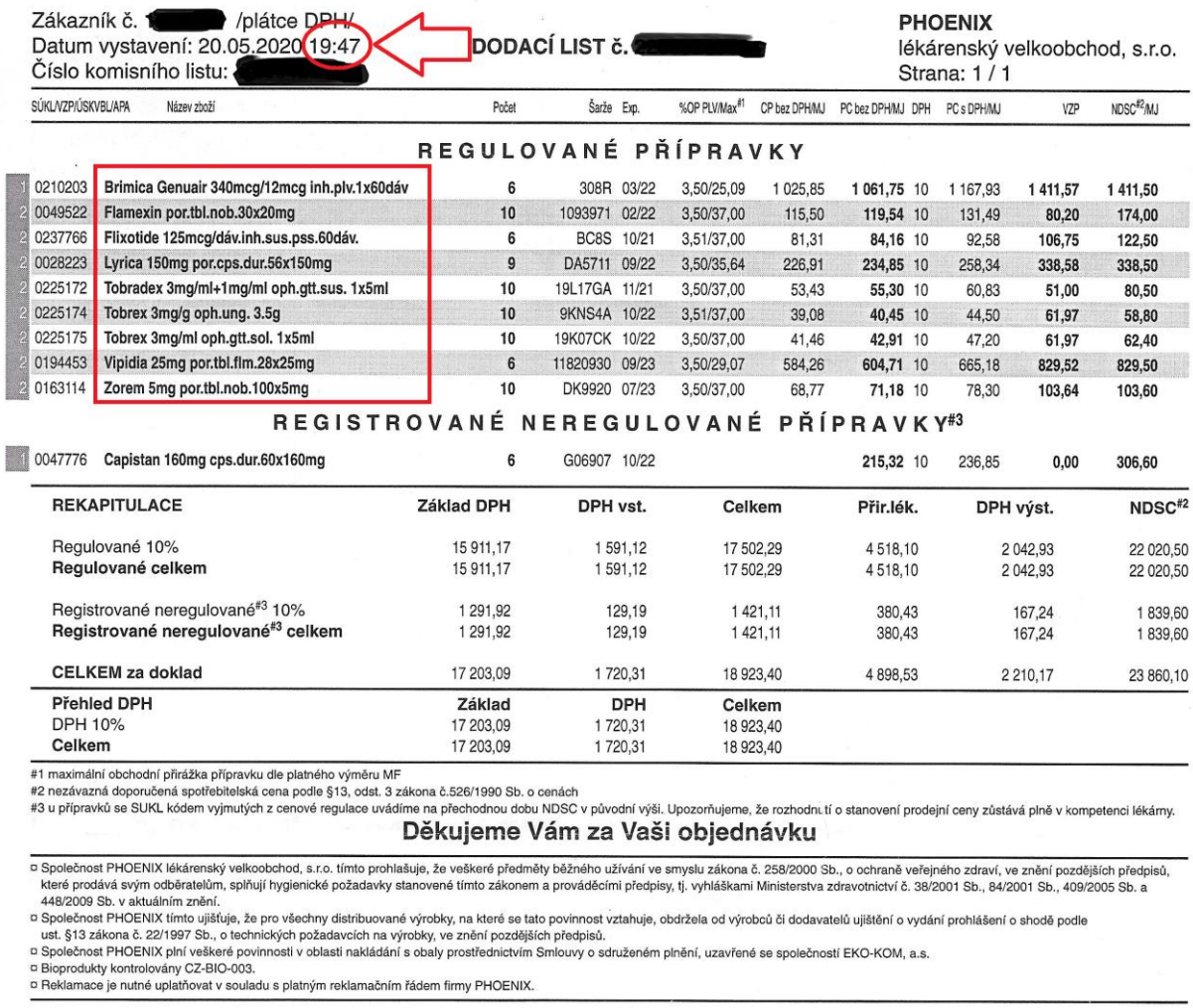
Due to the profit gained on provisions for buying out medicinal products for export, pseudo-pharmacies gain an unfair competitive advantage over regular pharmacies. The amount of money gained on provisions was in the case that I documented approximately 8.000 EUR per month. The provision amounted to 10% of the value of medicinal products for export.

In the case that I documented, the medicinal products were bought from PHOENIX and then sold as unnecessary stock to MERKUR Pharma, s.r.o.

In the following delivery note, we can observe several interesting points about the daily practice of parallel trade. The orders at PHOENIX's ordering platform are closed daily at 8 p.m., the order was placed just a few minutes before the closing. This is to avoid a mixture of medicinal products that the pharmacy wants to use for its patients and those that go for export. If an order is placed earlier during the day, delivery notes are connected to one longer note. Then, the pharmacy would need to acknowledge its reception in the pharmaceutical software. The pharmacy wants to avoid any official traces of the reception of the medicinal products for export.

Thus, it is placed on a separate delivery note, so this delivery note would serve only for the invoicing of these medicinal products between the parties that are engaged in parallel trade. We can see that this delivery note includes Flixotide 125 mcg inhaler and other medicinal products, which are also included in the order sent by Merkur Pharma s.r.o. to pharmacies. These medicinal products are unavailable for regular pharmacies. Only pharmacies with "VIP access" can order them from PHOENIX.

Figure 15: *A delivery note from PHOENIX to a pharmacy containing medicinal products for export*



Zákazník č. [redacted] /plátce DPH/
Datum vystavení: 20.05.2020 19:47
Číslo komisního listu: [redacted]

DODACÍ LIST č. [redacted]

PHOENIX
lékárenský velkoobchod, s.r.o.
Strana: 1 / 1

	SÚKL/VZP/ÚSKVBL/APA	Název zboží	Počet	Šarže	Exp.	%OP PLV/Max#1	CP bez DPH/MJ	PC bez DPH/MJ	DPH	PC s DPH/MJ	VZP	NDSC#2/MJ
		REGULOVANÉ PŘÍPRAVKY										
1	0210203	**Brimica Genuair 340mcg/12mcg inh.plv.1x60dáv**	**6**	308R	03/22	3,50/25,09	1 025,85	**1 061,75**	10	1 167,93	**1 411,57**	**1 411,50**
2	0049522	**Flamexin por.tbl.nob.30x20mg**	**10**	1093971	02/22	3,50/37,00	115,50	**119,54**	10	131,49	**80,20**	**174,00**
2	0237766	**Flixotide 125mcg/dáv.inh.sus.pss.60dáv.**	**6**	BC8S	10/21	3,51/37,00	81,31	**84,16**	10	92,58	**106,75**	**122,50**
2	0028223	**Lyrica 150mg por.cps.dur.56x150mg**	**9**	DA5711	09/22	3,50/35,64	226,91	**234,85**	10	258,34	**338,58**	**338,50**
2	0225172	**Tobradex 3mg/ml+1mg/ml oph.gtt.sus. 1x5ml**	**10**	19L17GA	11/21	3,50/37,00	53,43	**55,30**	10	60,83	**51,00**	**80,50**
2	0225174	**Tobrex 3mg/g oph.ung. 3.5g**	**10**	9KNS4A	10/22	3,51/37,00	39,08	**40,45**	10	44,50	**61,97**	**58,80**
2	0225175	**Tobrex 3mg/ml oph.gtt.sol. 1x5ml**	**10**	19K07CK	10/22	3,50/37,00	41,46	**42,91**	10	47,20	**61,97**	**62,40**
2	0194453	**Vipidia 25mg por.tbl.flm.28x25mg**	**6**	11820930	09/23	3,50/29,07	584,26	**604,71**	10	665,18	**829,52**	**829,50**
2	0163114	**Zorem 5mg por.tbl.nob.100x5mg**	**10**	DK9920	07/23	3,50/37,00	68,77	**71,18**	10	78,30	**103,64**	**103,60**
		REGISTROVANÉ NEREGULOVANÉ PŘÍPRAVKY#3										
1	0047776	**Capistan 160mg cps.dur.60x160mg**	**6**	G06907	10/22			**215,32**	10	236,85	**0,00**	**306,60**

REKAPITULACE	**Základ DPH**	**DPH vst.**	**Celkem**	**Přir.lék.**	**DPH výst.**	**NDSC#2**
Regulované 10%	15 911,17	1 591,12	17 502,29	4 518,10	2 042,93	22 020,50
Regulované celkem	15 911,17	1 591,12	17 502,29	4 518,10	2 042,93	22 020,50
Registrované neregulované#3 10%	1 291,92	129,19	1 421,11	380,43	167,24	1 839,60
Registrované neregulované#3 celkem	1 291,92	129,19	1 421,11	380,43	167,24	1 839,60
CELKEM za doklad	17 203,09	1 720,31	18 923,40	4 898,53	2 210,17	23 860,10

Přehled DPH	**Základ**	**DPH**	**Celkem**
DPH 10%	17 203,09	1 720,31	18 923,40
Celkem	17 203,09	1 720,31	18 923,40

#1 maximální obchodní přirážka přípravku dle platného výměru MF
#2 nezávazná doporučená spotřebitelská cena podle §13, odst. 3 zákona č.526/1990 Sb. o cenách
#3 u přípravků se SUKL kódem vyjmutých z cenové regulace uvádíme na přechodnou dobu NDSC v původní výši. Upozorňujeme, že rozhodnutí o stanovení prodejní ceny zůstává plně v kompetenci lékárny.

Děkujeme Vám za Vaši objednávku

- Společnost PHOENIX lékárenský velkoobchod, s.r.o. tímto prohlašuje, že veškeré předměty běžného užívání ve smyslu zákona č. 258/2000 Sb., o ochraně veřejného zdraví, ve znění pozdějších předpisů, které prodává svým odběratelům, splňují hygienické požadavky stanovené tímto zákonem a prováděcími předpisy, tj. vyhláškami Ministerstva zdravotnictví č. 38/2001 Sb., 84/2001 Sb., 409/2005 Sb. a 448/2009 Sb. v aktuálním znění.
- Společnost PHOENIX tímto ujišťuje, že pro všechny distribuované výrobky, na které se tato povinnost vztahuje, obdržela od výrobců či dodavatelů ujištění o vydání prohlášení o shodě podle ust. §13 zákona č. 22/1997 Sb., o technických požadavcích na výrobky, ve znění pozdějších předpisů.
- Společnost PHOENIX plní veškeré povinnosti v oblasti nakládání s obaly prostřednictvím Smlouvy o sdruženém plnění, uzavřené se společností EKO-KOM, a.s.
- Bioprodukty kontrolovány CZ-BIO-003.
- Reklamace je nutné uplatňovat v souladu s platným reklamačním řádem firmy PHOENIX.

The difference between prices in Germany and Czechia creates an enormous margin for parallel exporters and importers.

Zorem 5 mg 100 tablets is in Germany sold under the brand name Norvasc. The price of Zorem 5 mg 100 tablets in Czechia is for a patient 3,5 EUR. In Germany, the price of Norvasc 5 mg 100 tablets is 41,93 EUR.

The price of Lyrica 150 mg por.cps.dur. 56 capsules in Czechia is for a patient is 12 EUR. Lyrica is sold in Germany under the same brand name. In Germany, the same medicinal product Lyrica 150 mg por.cps.dur. 56 capsules cost 45,12 EUR.

It is evident that such a great difference has no economic explanation other than the targeted price regulation. Although the price differences are enormous, the benefit for consumers is on the basis of empirical evidence disputed. The ones who benefit the most are companies and people, who are involved in the parallel trade.

Therefore, it is no wonder that parallel exporters can afford to pay 10% provision to pseudo-pharmacies in order to get access to the medicinal products that are of interest for parallel trade.

The amount of the provision is so high that regular pharmacies do not have any legal options to compete with pseudo-pharmacies. Pseudo-pharmacies can afford to pay higher salaries, get better conditions from distributors and wider access to medicinal products including “VIP access” and also provide discounts for patients, which a regular pharmacy cannot afford.

Pseudo-pharmacies gain an unfair advantage through which we can observe unavoidable structural changes in the pharmaceutical market. These structural changes, which occur as a result of an uncritical appraisal of parallel trade by the European Union, directly infringe with the right to health care as they decrease the availability of medicinal products for EU citizens.

As a result of parallel trade, there are shortages of medicinal products and an evident exodus of regular pharmacies in member states of the EU with lower price levels of medicinal products. For example, in Czechia, the amount of independent pharmacists is

constantly being reduced, while chain pharmacies including PHOENIX's brand BENU are increasing their number.[113]

Some countries such as Poland or Hungary adopted strict regulative measures to avoid falling numbers of regular pharmacies. These measures are not directly connected to the issue of parallel trade but rather to Poland's and Hungary's general resistance to foreign capital owners. Yet, it still has a shared denominator in the EU single market rules, which allow companies with significant market power to even intensify their position against pharmacies owned by independent pharmacists. In Hungary, the "ownership law" was adopted, which was primarily aimed to reduce the ownership of foreign companies in local pharmacies. [114]

4. Falsified medicinal products and illegal distribution chains

The second part of my thesis consists of an analysis of illegal practices related to the distribution of medicinal products. I will focus especially on an illegal practice called "backpacking". I will also elaborate on the effectiveness of policy instruments against falsified medicinal products.[115] In the case I investigated, illegal practices in the distribution of medicinal products were conducted by the companies, which were involved in parallel trade through pseudo-pharmacies. The personal and material involvement of parallel traders in illegal practices in the distribution of medicinal products poses a threat to public health.

Parallel trade is mentioned as one of the boosters of counterfeit medicinal products. The Organization for Economic Cooperation and Development evaluated the value of

[113] The virtual map of pharmacies is available at D. Chripák, J. Nevyhoštěný, 'Mapa: V Česku je 2755 lékáren, jen deset jich však má nonstop. Leckde mají lidé smůlu', Aktuálně.cz, 2 March 2019, https://zpravy.aktualne.cz/ekonomika/lekarny-v-cesku-prehled-mapa-hustota-seznam/r~ad3e1e4a38dd11e98a200cc47ab5f122/, (accessed 8 June 2020).

[114] S. Michalopoulos, 'Commission silent over Hungary's pharmacy ownership law', EURACTIV, 21 March 2017, https://www.euractiv.com/section/health-consumers/news/commission-silent-over-hungarys-pharmacy-ownership-law/, (accessed 8 June 2020).

[115] W. L. Hamilton, C. Doyle, M. Halliwell-Ewen et al., 'Public health interventions to protect against falsified medicines: a systematic review of international, national and local policies', *Health Policy and Planning*, vol. 31, no. 10, 2016, pp. 1448–1466.

counterfeit goods in 2008 at about 250 billion US dollars. Counterfeit of medicinal products is one of the fastest-growing areas.[116]

4.1.1 The legal framework of the European Union

4.1.1.1 The Falsified Medicines Directive and Delegated Regulation

At the EU level, the Commission drafted the Falsified Medicines Directive (Directive 2011/62/EU) and Delegated Regulation that came into effect in February 2019 for all member states of the European Union. Apart from the member states of the EU, also four members of the European Free Trade Area (Iceland, Norway, Liechtenstein and Switzerland) decided to adhere to the rules specified by FMD.

The FMD was drafted as a crucial policy instrument against falsified medicinal products entering the distribution chain of medicinal products.[117] It provides detailed specifications of safety features (mainly a 2D barcode and anti-tampering device) that need to be implemented on the box by the manufacturer in order to prevent counterfeit medicinal products to reach patients. However, there are numerous issues with its implementation, for example in Poland.[118]

The primary focus of the FMD is a legal supply chain. What does that mean? The supply chain starts with a pharmaceutical company, which produces a medicinal product in a box with safety features mentioned above. Then this medicinal product is transported to a distributor who is responsible for an entry check of medicines and distribution to pharmacies and other health care providers. Pharmacies are again responsible for an entry

[116] Organization for Economic Cooperation and Development, 'Magnitude of counterfeiting and piracy of tangible products: an update', 2009, http://www.oecd.org/dataoecd/57/27/44088872.pdf (accessed 6 June 2020)

[117] Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending directive 2001/83/EC on the community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products text with EEA relevance OJ L 174.

[118] P. Merks, D. Swieczkowski, M. Byliniak, et al., 'The European Falsified medicines directive in Poland: background, implementation and potential recommendations for pharmacists', *European Journal of Hospital Pharmacy*, vol. 25, no. 1, 2018, pp. 1–6.

check of each box and also for the last check when the medicine is finally given to the patient.

4.1.1.2 Problems with implementation

The FMD specified a number of technical provisions applicable at various stages of the distributional path of a medicinal product.

Several problems occurred with barcodes. It turned out that they contain mistakes due to which in the beginning about 20% of them could not be verified in the pharmaceutical software. The regulation of dispensing also created problems in pharmacies that need to transfer medicinal products between themselves such as hospital pharmacies.[119]

European Medicines Verification Organisation (EMVO), which is a Belgian non-profit organisation representing stakeholders united in securing the legal supply chain from falsified medicines, stated that over 30,000 community pharmacists, hospitals and dispensing doctors across the EU had not yet connected with their respective national European Medicines Verification Systems.[120]

4.1.2 Illegal activities

4.1.2.1 „Backpacking" and corruption practices, the case of Czechia

Here I would like to introduce a corruption practice called informally "backpacking". "Backpacking" literally stands for illegal transportation of medicine in bags or backpacks from pharmaceutical representatives to doctors to get economic profit for all actors involved in the chain of "backpacking".

There are three important actors in this corruption practice: doctors, pharmaceutical companies represented by pharmaceutical representatives, and pharmacies.

[119] Merks, pp. 4-5.

[120] EMVO MONITORING REPORT, European Medicines Verification Organisation, 2019, https://emvo-medicines.eu/new/wp-content/uploads/2019CW41_EMVO-Monitoring-Report_Final.pdf, (accesed 12 June 2020)

How does “backpacking” work and why shall we examine whether it violates the right to health care?

The practice of “backpacking” is the following:

Instead of giving a prescription to patients, the doctor gives them directly the medicine while he or she receives a provision in the form of money, paid vacation or material benefits such as a television or a computer from the pharmaceutical company, which produces that particular medicine. This scheme typically applies only to medicinal products fully covered by health insurance so that the doctor does not have to receive money from the patient. The doctor keeps prescriptions that he usually sends through the pharmaceutical representative to a pharmacy, which then creates a falsified invoice to a health insurance company based on the false claim that the medicine had been given to the patient in the pharmacy.

This illegal practice has several serious consequences. The separation of doctors, pharmaceutical companies and pharmacies is like a separation of powers in a state.

Firstly, the doctor selects the medicine on the grounds of how big the provision is instead of the best interest of the patient. Different doctors have a different threshold of how far they choose to go. I mapped a case where a higher dosage was given by the doctor to a patient due to the fact that the price of this medicine with 10 mg of an active substance in one pill was significantly higher than the generally recommended initial dosage of 5 mg. In a case like this, the doctor receives higher provision (as provisions are typically calculated based on the price of the medicine). The doctor chose to adopt this illegal and unethical approach although it was strictly against the general medical recommendations on the initial dosage that the patient should have started with. The result was that the patient started throwing up after the first pill and subsequently stopped using the medicine. Therefore, the whole treatment turned out to be ineffective.

Secondly, those medicines are not part of an official distribution chain, therefore they can be easily substituted for falsified medicine or simply they can be kept in inappropriate conditions. During my encounter with this illegal practice, I took photos of medicines

transported in plastic bags in the hot summer. Inappropriate means of transport can degrade the effectiveness and health safety of medicines.

Thirdly, there is an unfair competition in the pharmaceutical market from which those who commit illegal actions benefit. They can economically ruin the competitors who act in accordance with the law. If doctors do not give patients prescriptions, then there are fewer patients coming to pharmacies. At the same time, pharmacies, which create falsified invoices to health insurance companies receive illegal income.

Figure 16: *Photo no. 1 of medicinal products transported in hot summer as a part of an illegal distributional chain*

Figure 17: *Photo no. 2 of medicinal products transported in hot summer as a part of an illegal distributional chain*

Figure 18: *Photo no. 3 of medicinal products transported in hot summer as a part of an illegal distributional chain*

Figure 19: *Photo no. 4 of medicinal products transported in hot summer as a part of an illegal distributional chain*

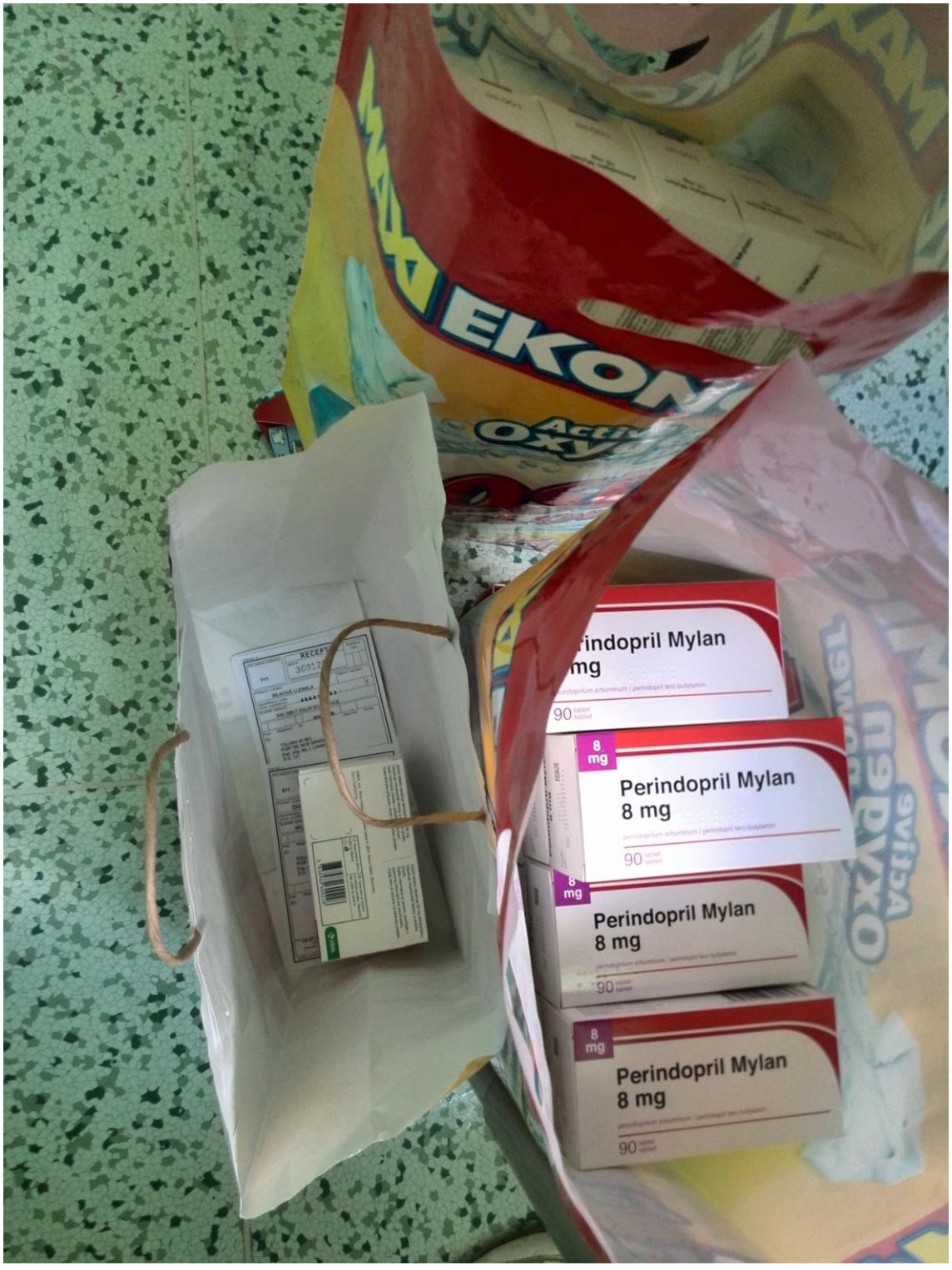
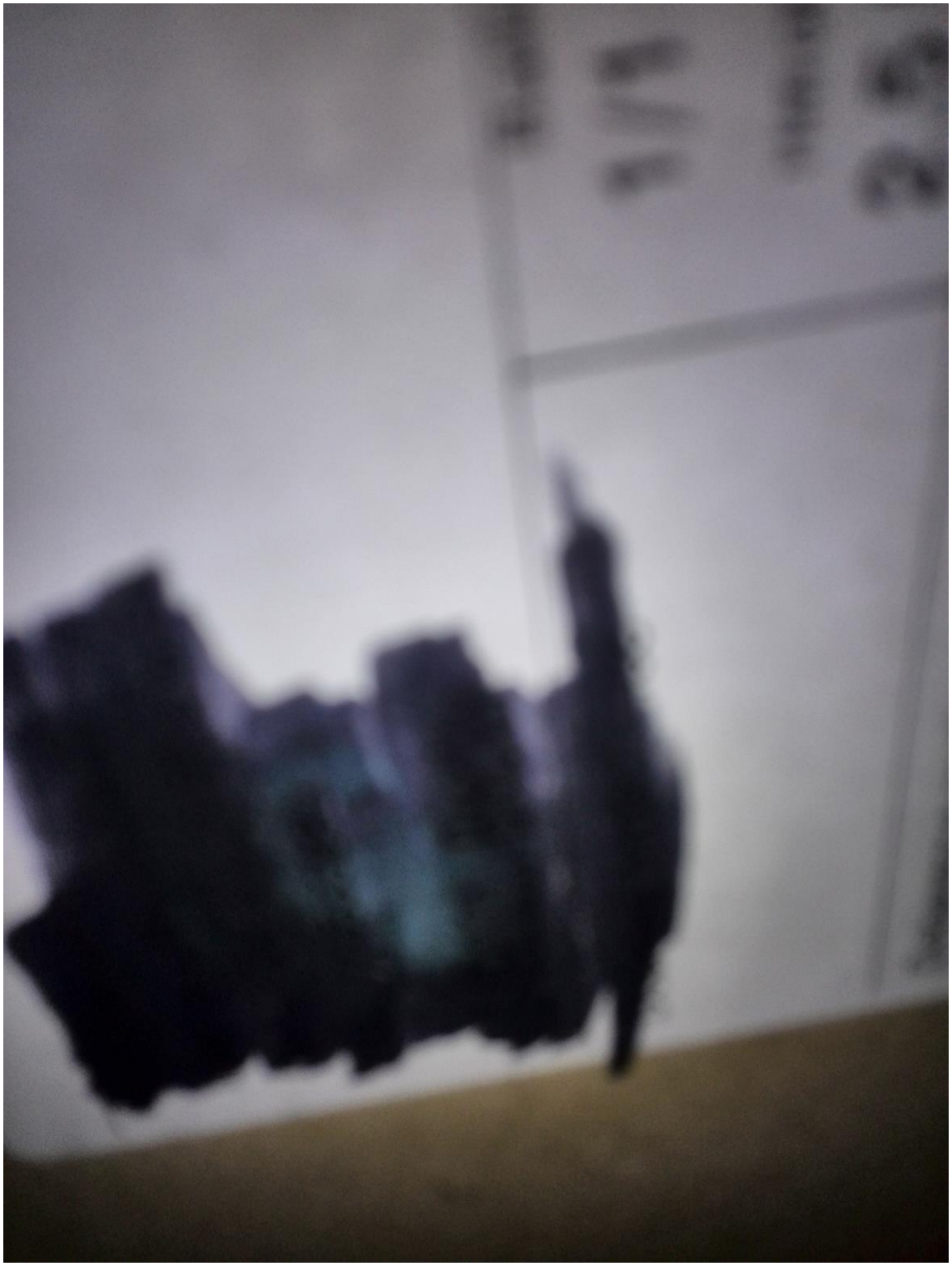


Figure 20: *Photo no. 5 of medicinal products transported in hot summer as a part of an illegal distributional chain*

The sender’s identification was darkened so it would not be readable.

Figure 21: *Photo no. 6 of medicinal products transported in hot summer as a part of an illegal distributional chain*



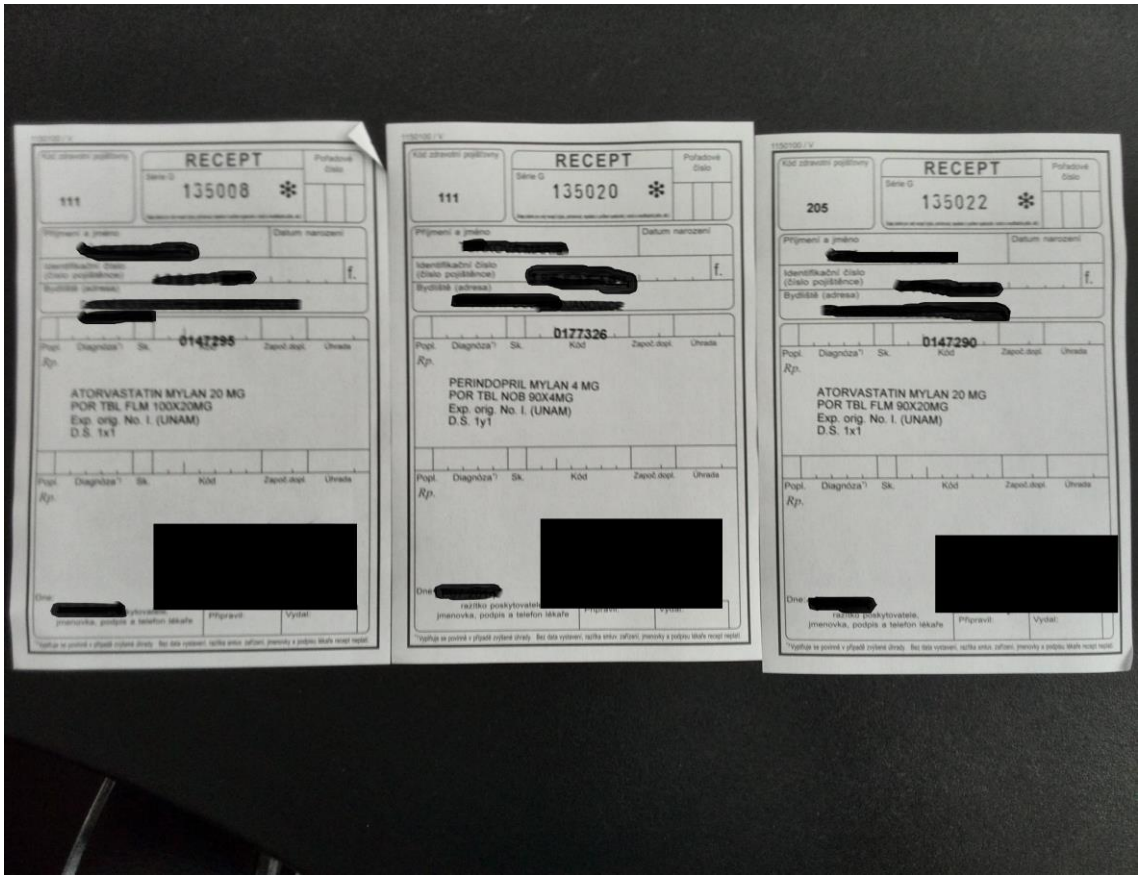
“Backpacking” is often done by the representatives of distributors that are engaged in parallel trade. In some cases, there are also pharmaceutical companies involved. They see in “backpacking” a chance to strengthen their position in the market.

Below is the business card of the pharmaceutical representative who negotiated with the doctor the conditions of “backpacking”. Doctors similarly as pharmacies receive 10% from the price of the medicinal product.

Figure 22: *Photo no. 7 the business card of the pharmaceutical representative*

The doctor does not give prescriptions to the patient but he or she gives directly the medicinal product for which he or she receives the provision. The doctor keeps the prescriptions and handles them usually once a month to the representative of the distributor, who then gives them to the pseudo-pharmacy, which creates a false invoice to the health insurance company claiming that it was sold in the pharmacy.

Figure 23: *Photo no. 8 prescriptions kept at the doctor's office to be exchanged for medicinal products*



5. Do legal instruments of the EU in the field of parallel import and export of medicinal products violate article 35 of the Charter of Fundamental Rights of the European Union on the right to health care?

At the beginning of my thesis, I outlined the problem. If there are trade policies at the EU level, which enable distributors of medicinal products to import and export medicinal products with no regards to their overall availability for patients in member states and thus cause a shortage, it is important to examine whether the EU does not violate article 35 of the CFR by having in place legal instruments that do not ensure a high level of human health protection.

In the chapter focused on the legal framework of health policymaking within the EU, I defined the responsibilities of the EU with regard to the right to health care.

Although there is no uniform European health care system under the regulatory framework of the EU, it is responsible for the legal instruments, which regulate the parallel trade of medicinal products.

Starting from the paradigm of parallel trade, the EU is responsible for keeping an uncritical approach to parallel trade as a beneficial state of play for consumers. In my thesis, I showed that parallel trade can lead to serious shortcomings. It can benefit companies that import and export medicinal products but it can make consumers in both short- and long-term worse off. This is especially the case when there is a great discrepancy in prices of medicinal products among member states. If the price gap is created through artificial means, e.g. price regulation by a state, then the consumers from countries with lower prices of medicinal products are paradoxically worse off. They are likely to experience a shortage of medicinal products. Furthermore, in countries with lower price levels such as Czechia, I have shown on a case study that companies in the pharmaceutical market started applying various illegal practices to secure the access to medicinal products for parallel traders and exclude consumers because the profit they can make due to the artificial price gap is enormous. Thus, the availability of key medicinal products is reduced and these medicinal products are inaccessible in regular pharmacies.

I have proved that the biggest distributor of medicinal products in the European Union, PHOENIX group uses a discriminatory ordering platform in Czechia, which provides privileged access to medicinal products for export to a limited number of VIP pharmacies. These pharmacies then sell these medicinal products to another distributor who then exports them to other member states.

The member states do not have the competence to regulate the rules on trade and competition, which are set out in TFEU as listed in the chapter on the legal framework. In the recent draft report of the ENVI Committee, the European Parliament acknowledged that shortages of medicinal products are a problem, which has no adequate solution at the national level.[121]

The Union is according to article 35 of the Charter of Fundamental Rights of the European Union responsible to ensure a high level of human health protection in the definition and implementation of all the Union's policies and activities. The Union is consequently obliged to regulate the trade of medicinal products, so it would not limit access to health care. It was shown that parallel trade can lead to shortages of medicinal products. It was also shown that these shortages are not a problem of an individual member state but rather a systematic downside of the Union's trade rules. Therefore, the legal instruments, specifically trade rules that enable parallel traders to export and import medicinal products with no regards on their accessibility for patients in member states violate article 35 of the CFR because the European Union did not ensure a high level of human health protection in the definition and implementation of all the Union's policies and activities.

This interpretation of the right to health care in article 35 of the CFR as encompassing accessibility to medicinal products for patients is in line with the interpretation of the right to health in General Comment No. 14. GC No. 14 set out that under the obligation to respect, states parties are obliged to refrain from denying, prohibiting or delaying access

[121] DRAFT REPORT of 30 April 2020 on the shortage of medicines - how to deal with an emerging problem (2020/0000(INI)), Committee on the Environment, Public Health and Food Safety, European Parliament, paragraph 15.

to medicinal products or health services.[122] As a violation of the obligation to respect, the GC No 14 recognizes the suspension of legislation or the adoption of laws or policies that interfere with the enjoyment of any of the components of the right to health.[123] If trade policies regularly result in a shortage of medicinal products, then the state is obliged to refrain from such trade policies. As I have concluded in the chapter on parallel trade, shortages of medicinal products are a systematic issue at the level of the European Union. This situation is acknowledged also by the ENVI Committee of the European Parliament. Therefore, it is the Union that needs to adopt trade policies, which do not cause shortages of medicinal products. If the EU does leave trade policies that lead to shortages of medicinal products in place, then it breaches the obligation to respect article 35 of the CFR.

Similarly, also the obligation to fulfill as specified in the GC No 14 is relevant in the case of shortages of medicinal products. The GC No 14 considers as the violation of the obligation to fulfill, namely, "the failure to take measures to reduce the inequitable distribution of health facilities, goods and services."[124] As I have shown in the chapter on parallel trade and in the case study, the biggest distributor of medicinal products in Europe PHOENIX group uses a systematic mechanism to deny the access to medicinal products, which are of interest for parallel trade, to regular pharmacies. Parallel trade motivates companies to restrict access to medicinal products for regular pharmacies and ordinary citizens in order to maintain access to these products only for parallel traders who can gain high profits from the price gap of medicinal products among member states. The EU violated the obligation to fulfill article 35 of the CFR when it did not define and implement policies for the prevention of shortages of medicinal products and unequal access to medicinal products.

[122] CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12), Adopted at the Twenty-second Session of the Committee on Economic, Social and Cultural Rights, on 11 August 2000, paragraph 34.

[123] Ibid, paragraph 50.

[124] Ibid, paragraph 52.

General Comment No. 14 specifies that states need to ensure equal access for all to health care and to the underlying determinants of health.[125]

According to GC No 14, the violation of the obligation to protect consists not only of willful actions but also "omissions as the failure to regulate the activities of individuals, groups or corporations so as to prevent them from violating the right to health of others.[126]

Access to medicinal products needs to be guaranteed under the principle of non-discrimination. States need to ensure that companies who sell medicinal products provide equal access to them. In the case study, it turned out, that distributors of medicinal products systematically deny access to medicinal products to regular pharmacies and citizens. Therefore, the EU violated the obligation to protect when it did not ensure that the distributors of medicinal products provide equal access to medicinal products.

6. Do illegal distribution chains violate article 35 of the Charter of Fundamental Rights of the European Union on the right to health care?

Illegal distribution chains possess a serious threat to public health care. The European Union acknowledged the necessity for verification mechanism to prevent falsified medicinal products through the adoption of the FMD. However, the FMD has a limited scope. It aims mainly to prevent patients from falsified medicinal products entering legal distribution chains. To put it in simple words, the FMD aims to assure that a particular medicinal product—at any stage of distribution process—is still the same medicinal product.

The threat to public health connected with the existence of illegal distribution chains does not rest only in the falsification of medicinal products.

[125] Ibid, paragraph 36.

[126] Ibid, paragraph 51.

As shown in the chapter on falsified medicinal products and illegal distribution chains, there are also other practices such as “backpacking”, against which the FMD has little to offer.

Furthermore, in the case study on Czechia, it turned out that there is a personal and material connection between parallel traders and illegal distribution chains. Companies involved in parallel trade were also involved in “backpacking” and corruption practices. This connection is alarming.

“Backpacking” and corruption practices are a serious threat to public health for the following reasons:

1. the doctor selects the medicinal product on the grounds of how big the provision is instead of the best interest of the patient; I mapped a case where a higher dosage was given by the doctor to a patient due to the fact that the price of this medicinal product with 10 mg of an active substance in one pill was significantly higher than the generally recommended initial dosage of 5 mg, the result was an ineffective treatment and unpleasant health consequences for the patient.
2. the medicinal products are transported with no regards to the rules on distribution of medicinal products, they are kept in inappropriate conditions; I took photos of medicinal products transported in plastic bags in the hot summer, this may seriously affect the health safety of medicinal products; there is also a danger that they can be substituted for falsified medicinal products;
3. those who benefit from unfair competition in the pharmaceutical market economically ruin regular pharmacies; if doctors do not give patients prescriptions, then there are fewer patients coming to regular pharmacies; at the same time, pharmacies, which create falsified invoices to health insurance companies receive illegal income.

Last but not least, illegal distribution chains lead to the reduction of the availability of the key medicinal products as described in the case study on Czechia. Although there are laws in place, which forbid pharmacies to distribute medicinal products, there is a systematic violation of these laws by parallel traders.

Under the obligation to protect the right to health care, the European Union is obliged to protect a high level of human health of EU citizens from the actions of third parties. For all the reasons stated above, it is clear that illegal distribution chains posses a great threat to public health. I have described in detail how illegal practices, specifically "backpacking" of medicinal products works. I have established that there is a personal and material connection of parallel traders and these illegal practices. The FMD is insufficient to eliminate illegal practices such as "backpacking". The European Union did not define or implement any legal instrument to systematically tackle illegal distribution chains, apart from the verification mechanism of medicinal products specified in the FMD. Therefore, the EU failed to protect the health of EU citizens codified in article 35 of the CFR when it did not prevent companies with cross-border reach to conduct illegal practices, which seriously threaten the health of EU citizens.

Conclusion

In my thesis, I examined trade-related challenges to the right to health care stated in article 35 of the Charter of Fundamental Rights of the European Union.

I comprehensively analyzed the parallel trade of medicinal products among the member states of the European Union. I conducted a case study in Czechia to evaluate the practices of parallel traders. I examined whether there is a causal link between shortages of medicinal products and parallel import and export of medicinal products and whether parallel trade leads to other shortcomings of the pharmaceutical market including illegal practices, which have overall consequences on the right to health care stated in article 35 of the Charter of Fundamental Rights of the European Union.

I focused on the human rights obligations of the European Union concerning the right to health care in article 35 of the CFR.

I tried to answer the following questions: Does parallel import and export of medicinal products within the Internal market of the EU lead to shortages of medicinal products in the member states? Do legal instruments of the EU in the field of parallel import and export of medicinal products violate article 35 of the Charter of Fundamental Rights of the European Union on the right to health care? Do policy instruments against falsified medicines effectively prevent illegal distribution chains? Do illegal distribution chains violate article 35 of the Charter of Fundamental Rights of the European Union on the right to health care?

The findings of my thesis suggest that parallel trade has several serious shortcomings, which endanger the equal access to medicinal products for EU citizens.

I have established a causal link between parallel trade and shortages of medicinal products. In the case study, I described in detail how parallel traders establish discriminatory access to medicinal products. I explained how parallel traders using illegal practices buy out medicinal products, which should have reached citizens in the respective member state with a lower price level and sell them with profit to a member state with a higher price level. The profit stays with the parallel trader and consumers in the member

state with a lower price level of medicinal products are worse off. I described that the current trade policies at the EU level and an artificial price gap in the prices of medicinal products among the member states such as in the case of Czechia and Germany are the sources of the motivation for parallel traders to adopt illegal practices and restrict access to medicinal products for citizens in the member state with a lower price level.

Furthermore, I identified illegal practices that directly endanger the health of EU citizens such as “backpacking”. This practice leads to the establishment of an illegal distribution chain, which can harm the patients in several aspects. Firstly, due to doctors who are motivated to prescribe medicinal products based on provisions for prescriptions and not with regards to the best interest of the patient. Secondly, due to the inappropriate conditions in which these medicinal products are kept. Thirdly, pseudo-pharmacies gain illegal income through falsified invoices to health insurance companies. Thus, they can economically ruin regular pharmacies in their neighborhood. Of attention to policymakers at the EU level should be the fact that there is a personal and material connection of parallel traders to illegal practices including “backpacking”.

I identified a violation of the right to health care in article 35 of the CFR by the European Union because it did not ensure the protection of a high level of human health in the definition and implementation of all Union policies and activities.

I concluded that the European Union violated the obligation to protect, respect and fulfill the right to health care. The obligation to protect was violated because the EU did not ensure that third parties with cross-border reach will not interfere with the right to health care by providing discriminatory access to medicinal products in member states. Furthermore, the obligation to protect was violated for the reason that the EU did not ensure that third parties with cross-border reach will not adopt practices, which constitute a danger to the health of EU citizens.

The obligation to respect was violated because the EU adopted trade policies, which lead to shortages of medicinal products in member states. The obligation to fulfill was violated by the EU for the reason that the EU did not adopt policies that would prevent shortages

of medicinal products, although it has the competence to do so through the change of the rules of the Internal Market of the EU.

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Appendix 1

List of medicinal products for export in February 2020 by Merkur Pharma, s.r.o.

Name of the medicinal product	Code	Price without VAT	Price with VAT	Amount
ABILIFY MAINTENA 400mg inj.plq.sur.isp.1x400r	210916	6730	7403	10
ABRAXANE 5MG/ML INF PLV SUS 1X100MG	29631	7100	7810	19
ACARIZAX 12SQ-HDM POR LYO 30	213247	1720	1892	20
ACTRAPID PENFILL 100IU/ML INJ SOL 5X3ML	26486	600	660	70
ADVAGRAF, 3MG CPS PRO 30	149149	2200	2420	10
ALVESCO 160 INHALER INH.SOL.PSS.60X160RG	224687	320	352	15
ARIMIDEX, 1MG TBL FLM 28	231850	490	539	10
ATIMOS 12 MCG INH SOL PSS 100X12RG	184319	600	660	20
ATROVENT 0.025% inh.sol.1x20ml	92351	95	104,5	100
AZARGA 10mg/ml + 5mg/ml oph.gtt.sus.1x5ml	500933	248	272,8	10
BERODUAL INH SOL 1X20ML	76496	122	134,2	50
BERODUAL N INH SOL PSS200 DAV	2679	200	220	50
BONDRONAT 6 MG/6 ML INF CNC SOL 1X6ML	26244	1180	1298	10
BRALTUS, 10MCG/DÁV INH PLV CPS DUR 30+1IN	313073	500	550	40
Budenofalk 2mg rektální pena rct.spm. 1x14 dáv	134861	1500	1650	20
Budiair inh.sol.pss. 200x200mcg	185108	300	330	7
CELLCEPT 250mg cps.100x250mg	27436	890	979	6
Cellcept 500mg por.cps.dur.50x500mg	27437	800	880	5
CERTICAN 0.25 MG TABLETY POR TBL NOB 60X0.2	17004	2900	3190	2
CERTICAN 0.75 MG TABLETY POR TBL NOB 60X0.7	16984	8000	8800	6
Cipralex 20mg/ml por.gtt.sol.1x15ml	123264	125	137,5	20
CISORDINOL DEPOT(CLOPIXOL dep.)inj.10x1ml/	86901	520	572	5
COAXIL tbl.obd.90x12.5mg	14808	85	93,5	20
DAXAS 500 mcg por.tbl.flm.30x500rg	167746	1020	1122	40
DAXAS 500mcg por.tbl.flm. 90x500RG	167747	3100	3410	50
DEPO-PROVERA INJ 1X1ML/150MG-STR	10754	300	330	20
DUODART 0,5 MG/0,4 MG POR CPS DUR 90	145988	1100	1210	40
DUORESP Spiromax 160mcg/4.5mcg inh.plv.1x1	194931	600	660	40
DUORESP Spiromax 320mcg/9mcg inh.plv.1x60d	194934	600	660	20
Eligard 22.5mg inj.pso.lqf.1x22.5mg van	125299	5000	5500	10
ELIGARD 45 MG 45MG INJ PSO LQF 1+1 II	125284	8200	9020	6

ELIQUIS 2.5mg por.tbl.flm.20x2.5mg	168326	410	451	40
ELIQUIS 5mg por.tbl.flm. 60x5mg	193745	1430	1573	50
ENSTILAR 50MCG/G+0,5MG/G DRM SPM 1X60(	103789	960	1056	20
Eucreas 50mg/1000mg por.tbl.flm.60	29740	680	748	20
FEMARA POR TBL FLM 30X2.5M	16469	450	495	20
FERINJECT INJ SOL 1X10ML	155379	2500	2750	10
FLAMEXIN tbl.30x20mg	49522	124	136,4	19
FLIXOTIDE 125 INHALER N, 125MCG/DÁV INH S	237766	90	99	15
FLUTIFORM 125/5mcg v 1 dávce inh.sus.pss. 12	165649	600	660	25
FLUTIFORM 250/10mcg v 1 dávce inh.sus.pss. 1	165650	1000	1100	25
FOSRENOL 1000MG ŽVÝKACÍ TABL.POR.TBL.MI	232948	4200	4620	30
FUCIDIN crm.1x15g 2%	84492	60	66	30
FUCIDIN ung.1x15g 2%	88746	55	60,5	40
Fycompa 2mg por.tbl.flm.7x2mg	185305	180	198	30
Fycompa 4mg por.tbl.flm.28x4mg	185307	1600	1760	20
Fycompa 6mg por.tbl.flm.28x6mg	185310	1850	2035	3
Galvus 50mg por.tbl.nob.56x50mg	29199	630	693	5
GENOTROPIN 36m.j.(12mg) inj.pso.lqf. 5x36 U	187295	36150	39765	5
GIOTRIF 30MG TBL FLM 28X1	194523	33800	37180	2
GRAZAX 75 000 SQ-T por.lyo. 10x10	100981	6300	6930	10
GRAZAX 75 000 SQ-T por.lyo. 3x10	100980	1800	1980	3
HULIO 40MG INJ.SOL. 2X0.8ML PFP	238197	12500	13750	10
HULIO, 40MG INJ SOL 2X0,8ML	238194	12500	13750	10
HUMATROPE INJ.SIC.36IU+solv.1	92320	6000	6600	2
HUMATROPE INJ.SIC.72IU+solv.	92323	13000	14300	2
IMRALDI, 40MG INJ SOL 2X(1X0,8ML)	222923	13900	15290	6
IMRALDI, 40MG INJ SOL 2X(1X0,8ML)	222421	13900	15290	3
IMURAN, 50MG TBL FLM 100	199647	340	374	20
INCRUSE 55MCG INH PLV DOS 1X30DAV	210035	680	748	30
INSUMAN COMB 25 INJ SUS 5X3ML/300UT	25704	600	660	10
INSUMAN Comb 25 inj.sus.5x3ml/300UT Solos	500845	600	660	10
INSUMAN Rapid 100IU/ml inj.sol5x3ml/300UT	500827	600	660	40
Invokana 100mg por.tbl.flm.30x100mg	194605	970	1067	20
Januvia 100mg por.tbl.flm.28x100mg	28740	730	803	30
JARDIANCE 10mg por.tbl.flm.30x1x10mg	210023	950	1045	10
LIXIANA 30MG TBL FLM 30	210612	870	957	10
LYRICA 225mg por.cps.dur. 56x225mg	26196	400	440	8
LYRICA 50mg por.cps.dur. 56x50mg	28213	200	220	40
MARCAINE 0.5% INJ SOL 5X20ML/100M	2439	280	308	5
MAXITROL oph.gtt.sus. 1x5ml	225168	64	70,4	30
Menopur 75 IU inj.pso.lqf.10+10x1ml	180902	4800	5280	10
MUSCORIL INJ. 6x2ml/4mg	107944	130	143	100
NEBIDO 1000MG/4ML INJ SOL 1X4ML	223477	2100	2310	15

NEUPRO 2mg/24H drm.emp.tdr.7x4.5mg	26076	200	220	10
NEUPRO 3MG/24H TDR EMP 28X6,75MG	500315	2200	2420	10
NEUPRO 4mg/24H drm.emp.tdr.28x9mg	26080	1500	1650	17
NOVORAPID inj.1x10ml/1KU	26786	450	495	20
NOXAFIL 100mg por.tbl.ent.24x100mg	210001	17500	19250	2
ORALAIR 300 IR 300IR SLG TBL NOB 30	209782	1650	1815	10
ORALAIR 300 IR 300IR SLG TBL NOB 90	209783	5400	5940	5
OTOBACID N, 0,2MG/G+5MG/G+479,8MG/G AU	232954	110	121	10
OZEMPIC, 0,25MG INJ SOL 1X1,5ML+4J	223052	1090	1199	10
Pentasa slow release tab.500mg por.tbl.ret.10	86616	740	814	10
PICOPREP prášek pro přípr.per.rozt. por.plv.so	160806	200	220	50
Pradaxa 110mg por.cps.dur.30x1x110mg	29327	700	770	20
PRADAXA 110mg por.cps.dur.60x1x110mg	29328	1300	1430	20
PRADAXA 150mg por.cps.dur.60x1x150mg	168373	1420	1562	10
PREDUCTAL MR por.tbl.ret.180x35mg	186665	375	412,5	20
PROLIA 60MG/ML INJ.SOL.1X1ML	167653	5200	5720	19
PULMICORT TURBUHALER 400MCG PLV INH 20(	69243	1240	1364	20
PULMICORT, 0,5MG/ML SUS NEB 20X2ML	235776	420	462	50
RAPAMUNE 0,5MG TBL OBD 100	167744	5000	5500	10
ROCALTROL 0.25 MCG POR CPSMOL30X0.25RG	14937	80	88	100
ROCALTROL 0.50 MCG POR CPS MOL 30X0.50	14938	98	107,8	20
ROSEMIG, 20MG NAS SPR SOL 2X0,1ML	237899	237	260,7	20
SANDIMMUN NEORAL 100MG CPS 50X100MG	15642	2000	2200	5
SANDIMMUN NEORAL 50 MG POR CPS MOL 50	15641	900	990	5
SEEBRI Breezhaler 44mcg inh.plv.cps.dur.30x4	193552	700	770	50
Simbrinza 10mg/ml + 2mg/ml oph.gtt.sus.1x5r	210078	310	341	20
Simbrinza 10mg/ml + 2mg/ml oph.gtt.sus.3x5r	210079	950	1045	20
SPIRIVA Respimat 2.5mikrogramu inh.sol.1x60	109810	740	814	30
SYMBICORT TURBUHALER 200/6 INH PLV 120 D	180087	650	715	100
SYMBICORT TURBUHALER 400/12 INH PLV 1X60	180081	650	715	100
TOBRADEX, 3MG/ML+1MG/ML OPH GTT SUS 1X	225172	60	66	100
TOVIAZ 4 MG POR TBL PRO 84X4MG	500370	1300	1430	5
TOVIAZ 8 MG POR TBL PRO 84X8MG	500369	2100	2310	5
TRAJENTA 5mg POR TBL FLM 30X5MG	168447	880	968	40
TRAJENTA 5mg por.tbl.flm.90x5mg	168451	2500	2750	10
UBRETID 5 MG 5MG TBL NOB 50	2130	250	275	20
UBRETID 5 MG POR TBL NOB 20X5MG	2360	100	110	10
ULTIBRO breezhaler 85/43mcg inh.plv.cps.dur	194361	1215	1336,5	20
Urizia 6mg/0.4mg por.tbl.frt.100x6mg/0.4mg	197787	1460	1606	10
Vagifem 10 mikrogramu vag.tbl. 18x0.01mg	145124	400	440	6
XALACOM oph.gtt.sol.3x2.5ml	103386	350	385	6

XARELTO 15 mg por.tbl.flm.28x15mg	168897	1380	1518	30
XARELTO 20mg por.tbl.flm.28x20mg	168903	1370	1507	70
XARELTO 20mg por.tbl.flm.98x20mg	168904	4700	5170	30
XEPLION 100MG inj.sus.pro. 1x100mg +2jehly	168089	9000	9900	11
XEPLION 150mg inj.sus.pro.1x150mg + 2jehly	168090	13000	14300	13
XEPLION 50mg inj.sus.pro.1x50mg + 2 jehly	168087	5100	5610	15
XYZAL 0.5MG/ML PER.ROZT.POR.SOL.1X200ML	62806	60	66	50
ZEBINIX 800mg por.tbl.nob.30x800mg	149145	2300	2530	50
Zineryt 40mg/12mg/ml drm.sol.1+1x30ml(plv.+sol	173200	190	209	50
Zoladex Depot 3.6mg imp.isp.1 (ZNC)	231859	1400	1540	15
ZOLADEX DEPOT, 10,8MG IMP ISP 1	0231858	5000	5500	8
ZOREM 5mg por.tbl.nob.100x5mg	163114	85	93,5	5
ZOREM 5mg por.tbl.nob.30x5mg	163112	30	33	10
ZYPADHERA 210mg inj.plq.sus.pro.1x210mg	500872	3600	3960	3
ZYRTEC por.tbl.flm.90x10mg	155686	260	286	10