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Parallel Trade of Pharmaceuticals and its Problems in the EU

How to address Shortages, Falsification Risks and Non-Transparency

Nathalja Nolen and Stephan Balling

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Parallel trade is a form of arbitrage: A product, sold by the manufacturer in country X at a lower price than in country Y, is bought by a dealer in country X and sold in country Y. It is particularly relevant for pharmaceuticals on the EU's internal market. This cepInput discusses basic options for addressing problems connected with parallel trade of pharmaceuticals.

Key Propositions

- Parallel trade of pharmaceuticals within the EU is connected with several problems, particularly pharmaceutical shortages, higher potential risk of falsified pharmaceuticals, non-transparent pricing and calculation problems for manufacturers.
- The significance of parallel trade of pharmaceuticals varies among EU countries. It is negligible in France and Italy while in Germany 8.5% of the pharmaceuticals sold are traded in parallel, and in Denmark the figure is 26.2%.
- The EU's position on the parallel trade in pharmaceuticals is contradictory: The EU wants both the free movement of medicines in the internal market and equal access to them for EU citizens.
- There are three basic options for addressing the problems caused by parallel trade: (1) exclusion of pharmaceuticals from the internal market rules, (2) open redistribution among national health systems by a subsidisation fund and (3) unitary pricing in the EU.
- None of these options resolves the problems caused by parallel trade, without causing other issues. A political debate is needed on what trade-offs should be made.

Content

Tables

1 Introduction

Parallel trade is a form of arbitrage: A product, sold by the manufacturer in country X at a lower price than in country Y, is bought by a dealer in country X and sold in country Y. The price difference must be high enough to allow for a profit after the deduction of all costs. Parallel trade is particularly relevant in the EU's pharmaceutical sector where it has led to a number of problems (Section 2). The EU, despite its limited competences, is trying to tackle these problems (Section 3). In order to initiate a discussion on parallel trade and its consequences, this cep**Input** sets out different approaches to addressing the problems caused by parallel trade (Section 4).

2 Parallel Trade in the Pharmaceutical Sector

2.1 The Reasons for Parallel Trade in the Pharmaceutical Sector

The pharmaceutical industry is a special sector in two respects: Firstly, innovative pharmaceutical companies incur high research and development costs for novel medicines. They only have an incentive to develop such medicines if they are likely to be profitable. Registering a patent allows pharmaceutical companies to set or negotiate monopolistic prices with national health systems. Secondly, in many cases, the buyer of a pharmaceutical product does not directly pay for it but is reimbursed by a national health system. Prices and reimbursement schemes vary considerably between countries in Europe: Prices are negotiated nationally or even regionally between the manufacturer and national insurers, be they public or private, depending on their ability to reimburse. Price differentiation allows companies to allocate contributions to research and development costs efficiently among different payers, which improves cost recovery.[1]

This results in considerable price differences between Member States. A price comparison of pharmaceuticals in 16 EU Member States in 2013 shows differences between 25% and 100% for two thirds and between 100% and 251% for one third.[2] Such price differences are a strong incentive for parallel trade: An importer, usually a wholesaler, purchases pharmaceuticals in a low-price country and then sells them in a high-price country.

2.2 Volume of Parallel Trade in the EU

In 2019, the total value of parallel imports of pharmaceuticals taking place in the European Economic Area (EEA) was € 5.7 billion.[3] Within the EU, the share of imported medicinal products in the respective national pharmaceutical markets varies greatly (see Table 1).[4] The high share in Denmark and Germany can be explained by their health policies. Imported medicines are given preferential treatment in Den-

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1 Towse, A. et al. (2015), "European Union Pharmaceutical Markets: A Case for Differential Pricing?", in: International Journal of the Economics of Business, Vol 22. No. 2, p. 263 (all sources of this cep**Input** were last accessed on 22 March 2021).

2 Vogler, S. et al. (2017), "Price comparison of high-cost originator medicines in European countries", in: Expert Review of Pharmacoeconomics & Outcomes Research, p. 222 and p. 228.

3 Weißenfeldt, F. (2020), "Parallelhandel mit Arzneimitteln", in: Pharm. Ind. 82, No. 10, p. 1274.

4 These numbers are taken from the European Federation of Pharmaceutical Industries (EFPIA) and the European Association of Euro-Pharmaceutical Companies (EAEPC), which are lobby groups, and may therefore not present a fully unbiased view.

mark and German law obliges pharmacies to sell (re-)imported medicines if their prices are below certain thresholds. In Germany this is called the "import promotion clause". The German health system uses imported medicines to reduce costs in the health system.[5]

Table 1: Shares of parallel imported medicines in national pharmaceutical markets (2013 or 2018) [6]

France	0.1 %	Belgium	2.1 %	Germany	8.5 %
Italy	0.4 %	Finland	2.2 %	Sweden	12.0 %
Austria	1.9 %	Ireland	6.0 %	Denmark	26.2 %
Poland	2.0 %	The Netherlands	7.9 %		

2.3 Consequences of Parallel Trade in the EU

Parallel trade, on the one hand, lowers expenditure on pharmaceuticals for high-price countries which is, of course, welcomed by them. The larger the share of parallel imported medicines, the greater this effect is. On the other hand, it has a number of negative consequences: In the single market it may particularly result in shortages of medicines in low-price, i.e. poorer, Member States and increase the risk of falsified medicines. Furthermore, parallel trade adds to the non-transparency of price structures and may cause certain difficulties for pharmaceutical companies regarding cost calculations.

(1) Shortages of Medicines

Parallel trade, i.e. exports of pharmaceuticals from low-price countries to high-price countries, may lead to shortages in the former unless the manufacturer is willing to make up for it and supply higher quantities of the product. The larger the volume of parallel trade the greater the problem of shortages. This effect has been observed in a number of Member States: Greece[7], Portugal and Central and Eastern European Member States.[8] These countries have implemented legislative measures to make the export of medicines more difficult. Slovakia, for example, created an obstacle to trade by imposing formality procedures on medicines.[9] In 2016, the EU Commission suspected Portugal and Slovakia of placing "unjustified restrictions" on the export of medicines which is also an indication of shortages.[10] There were similar complaints against Poland and Romania. None of them were pursued further; the EU Commission closed the infringement procedures in 2018.[11]

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5 Section 129 (1) (p. 1) (no. 2) SGB V; "Federal Government's answer to the FDP's parliamentary question of April 2019".

6 EFPIA (2020), "2018" p. 5; EAEPC (2013), "The Parallel Distribution Industry: a closer look at savings", p. 11 and p. 13; Les entreprises du médicament (leem) (2020), "Bilan économique Edition 2020", p. 40. Numbers of Italy and France are from 2013. All other numbers are from 2018. The number in France covers reimbursed products only.

7 A shortage of medicines for epilepsy occurred in 2008. The Guardian (2008), "Parallel trade in drugs puts EU patients at risk".

8 The Economist Intelligence Unit (2017), "Cancer Medicines shortages in Europe: Policy Recommendation to prevent and manage shortages", p.9; The Guardian (2008), "Parallel trade in drugs puts EU patients at risk"; European Parliament (2018), "Parliamentary questions".

9 European Commission (2018), "Infringement decisions".

10 The Economist Intelligence Unit (2017), "Cancer Medicines shortages in Europe: Policy Recommendation to prevent and manage shortages", p. 18.

11 European Commission (2018), "Infringement: Parallel trade of medicines: Commission closes infringement proceedings and complaints against Poland, Romania and Slovakia".

(2) Risk to the safety of pharmaceuticals

Parallel trade can increase the potential risk of falsified pharmaceuticals because extra steps are added to the supply chain through parallel imports.[12] Complex supply chains, routes of transport, changes of outer packaging and relabelling make it difficult for national authorities to trace the history of pharmaceuticals bought and sold by intermediaries in different EU Member States.[13] The EU has taken measures against falsified medicines through the Falsified Medicines Directive.[14] So far, however, this has not eliminated the problem completely.

(3) Lack of transparency and calculation problems

Prices in the pharmaceutical sector are not transparent. The negotiated prices that health insurers pay are generally not published. In Germany, for example, there are about 30,000 individual exclusivity contracts between health insurers and manufacturers, allowing for different prices and discounts that remain undisclosed.[15] Such lack of transparency protects the producers by blocking price signals to other insurers and other countries. Parallel trade adds to this lack of transparency because it is not made clear which insurer pays how much for pharmaceuticals traded in parallel. Individually negotiated contracts and parallel trade can also lead to calculation problems for the pharmaceutical companies because they do not know how much they will sell at what price or how much will be traded in parallel between which countries.

3 The Position of the European Union on Parallel Trade

The EU's position on parallel trade is characterised by two basic objectives that are somewhat contradictory:

Firstly, the principles and rules of the internal market must be observed. Parallel trade is considered compatible with the free movement of goods in the internal market [Article 34 Treaty on the Functioning of the European Union (TFEU)]. The EU Commission sees restrictions on parallel trade as one of the most serious violations of EU competition law.[16] Restrictions may exceptionally be introduced if justified by overriding requirements of public interest, for example the protection of human health and life, and if there are no other less restrictive means available to achieve that objective [Article 36 TFEU].[17] Export bans and notification/authorisation procedures related to exports of pharmaceuticals might be justified if considered suitable, proportionate and necessary for overriding requirements of public interest [Art. 36 TFEU].[18]

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12 BKA (2016), "Arzneimittelkriminalität: Ein Wachstumsmarkt", p. 50 f.

13 Muckenfuß, H. (2017), "Arzneimittelfälschungen in Parallelhandel", in: Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz, p. 1208.

14 European Commission (2021), "Medicinal products".

15 ABDA (2020), "DIE APOTHEKE – ZAHLEN, DATEN, FAKTEN 2020", p. 35.

16 Liberatore, F. (2014), "Restrictions on Parallel Trade of Pharmaceutical Products and EU Competition Law", p. 349.

17 European Commission (2018), "Infringement: Parallel trade of medicines: Commission closes infringement proceedings and complaints against Poland, Romania and Slovakia"; Affordable medicines Europe (2021), "What is parallel trade?"

18 European Commission (2015), "Study on enhanced cross-country coordination in the area of pharmaceutical pricing", p. XVII.

Secondly, every EU citizen should have equal access to safe pharmaceuticals.[19] The Commission acknowledges that shortages and falsified pharmaceuticals, caused by parallel trade, are detrimental to this objective, as Commissioner Andriukaitis declared in 2018.[20]

Healthcare policy in general, and both pricing and reimbursement schemes in particular, are the responsibility of the Member States [Art. 168 (7) TFEU]. Since the 1990s, discussions have taken place about negotiating pharmaceutical prices at EU level. The European Medicines Agency (EMA) has suggested extending its remit to include drug pricing and reimbursement. So far, however, there has been no agreement between individual EU Member States.[21]

Certain decisions can be made at EU level, such as the approval of pharmaceuticals which is largely the EMA's responsibility.[22] Many EU Member States have now committed to work together on healthcare issues, on a voluntary basis[23], in order to minimise any unintended effects of current national policies on access to pharmaceuticals in the EU.[24]

Recently, the EU Commission has intensified its calls for much closer cooperation: In September 2020, a new health program, "EU4Health", was adopted within the framework of "NextGenerationEU"[25] – a € 750 billion programme to ease the immediate economic and social effects of the COVID-19 pandemic. "EU4Health" will strengthen health security and prepare for future health crises. It will form the basis for a "European Health Union".[26]

In November 2020, the EU Commission published its ideas for a "Pharmaceutical Strategy for Europe", which is to form "a key pillar" of that "European Health Union". The strategy will ensure quality and safety for pharmaceuticals. Together with the EU Cancer Plan, the strategy aims to ensure that essential cancer drugs are available and affordable across the EU. The EU Commission criticises the fact that patients in the EU do not have equal access to pharmaceuticals and calls for joint public procurement as well as joint pricing and reimbursement negotiations at EU level. It announces its intention to foster transparency of price information in order to help Member States improve pricing and reimbursement decisions, also considering possible knock-on effects for innovation.[27]

The strategy regards shortages of pharmaceuticals in the EU as a "serious concern" with parallel trade as one of several reasons.[28] To address shortages, the EU Commission wants Member States to develop "guidelines, measures and tools" supported by EU4Health. The EMA is to evaluate supply capacity and

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19 European Commission (2020), "Affordable, accessible and safe medicines for all: the Commission presents a Pharmaceutical Strategy for Europe".
20 European Parliament (2018), "Parliamentary questions".
21 ZS (2021), "European drug pricing alliances: Force or farce?".
22 EMA (2021)", "What we do".
23 An example of voluntary cooperation is the exchange format for electronic health records which should facilitate cross-border healthcare. See: CEP (2019), "European Electronic Health Exchange Format".
24 European Commission (2021), "Cost-effective use of medicines".
25 European Commission (2021), "Recovery plan for Europe".
26 European Commission (2020), "State of the Union Address by President von der Leyen at the European Parliament Plenary".
27 European Commission (2020), "Pharmaceutical Strategy for Europe", p. 1-8.
28 The other reasons are: marketing strategies, scarce active pharmaceutical ingredients and raw materials, weak public service obligations and supply quotas or issues linked to pricing and reimbursement. See: European Commission (2020), "Pharmaceutical Strategy for Europe", p. 17.

mitigate shortages of crucial pharmaceuticals in times of a crisis.[29] Otherwise, parallel trade does not play a big role in the strategy.

4 Theoretical Options for Reform

The two fundamental objectives of the EU – (1) maintaining the free trade in pharmaceuticals in the internal market and (2) equal access to pharmaceuticals for all EU-citizens – are contradictory. One important reason for this is that parallel trade is caused by differing pricing and reimbursement schemes in the Member States. Other problems caused by parallel trade – risk of falsified pharmaceuticals, non-transparency of pricing and calculation risks for pharmaceutical producers also have to be addressed.

There are three basic options for tackling these problems: the exclusion of pharmaceuticals from the internal market rules (4.1), open redistribution among the national health systems by some form of a subsidisation fund (4.2), and a unitary price that has to be paid everywhere in the EU (4.3).

4.1 Exclusion of Pharmaceuticals from the Internal Market Rules

Under this option, the EU would exclude pharmaceuticals from the internal market rules so that, in order to avoid shortages, EU Member States would be allowed to prevent parallel trade by prohibiting the export of pharmaceuticals that had been imported. This of course means that the first objective of the EU would not be achieved; the free movement of goods would be abolished for that sector.

The EU's second objective, that every EU citizen should have equal access to pharmaceuticals, appears at first sight to be achieved: If a Member State is allowed to ban exports, shortages that are caused by parallel trade can be prevented. This is not the end of the story, however, because parallel trade is not the only possible reason for shortages. Suppose that a poor country with a large population is able to negotiate a substantial price discount with a pharmaceutical manufacturer, whilst another similarly poor but small country is unable to achieve favourable conditions making the pharmaceutical unaffordable for the small country. In this case, imports from the large country may also allow the pharmaceutical to be supplied to the small country.[30] In this case, it is not parallel trade but the suppression of parallel trade that leads to shortages.

Furthermore, the problems of falsified pharmaceuticals, non-transparency and incorrect price calculations will evidently not be eased if Member States are allowed to impose ad-hoc export bans on pharmaceuticals.

Additionally, trade restrictions within the EU are difficult to enforce and may cause even bigger problems. To actually avoid cross border transfers of pharmaceuticals, border controls would probably be necessary which would cause huge economic transaction costs with a high probability of illegal smuggling. The negative effects of national border controls became evident during the COVID-19 crisis in spring 2020, when certain Member States restricted the export of protective equipment.[31] As supply

[29] European Commission (2020) "Pharmaceutical Strategy for Europe", p. 17 and 19.
[30] McKeith S. (2013), "Pharmaceutical Patents in Developing Nations: Parallel Importation and the Doctrine of Exhaustion", in: African Journal of Legal Studies 6, p. 289 and 301.
[31] Mayer Brown (2020), "EU and EU Member States Impose COVID-19-Related Export Restrictions on Medical and Protective Equipment".

and production chains do not end at national borders, closed borders may reduce or stop overall production and therefore enlarge the problem of shortages. This may well affect many products, among them pharmaceuticals.

4.2 European Fund for Redistribution among National Health Systems

Under this option a European redistribution fund would be established to resolve or at least dampen problems of shortages caused by parallel trade. The fund would transfer financial resources to the health systems in need so that they could buy pharmaceuticals on the free market. The fund would be aimed at shortages caused by parallel trade.

This would guarantee the free movement of pharmaceuticals in the internal market. Whether it would also achieve the second objective, i.e. equal access to pharmaceuticals by all EU citizens, would depend on a number of prerequisites. First and foremost, it would depend on the size of the fund and on the volume of parallel trade. Second, it would depend on the fund's internal organisation and on the way the resources are managed in the recipient countries. These are complex issues for several reasons: The national health systems are very diverse, and much would depend on who at the national level would receive the money and how the limited quantity of medicines would be purchased and where. Certain competences would have to be given to the EU and its institutions, probably the European Medicines Agency (EMA) in particular. It would have to play a central role in defining and managing shortages.[32] Currently, shortages related to economic or business causes – such as parallel trade – are outside the remit of the EMA.[33]

Another question to be answered is how the fund would be financed. According to the Commission's Pharmaceutical Strategy, pharmaceuticals should be available and affordable to every EU citizen, and the programme "EU4Health" should form the "key pillar" of a "European Health Union".[34] Therefore, resources from "EU4Health" could be used to finance a fund to tackle pharmaceutical shortages.

The problem of falsified pharmaceuticals, and the issues around non-transparent pricing and calculation risks for pharmaceutical companies, would not be resolved by a fund. In this case, the approval and surveillance system for pharmaceuticals in the EU would have to be strengthened, as touched on in the EU Pharmaceutical Strategy by reference to the goal of a "European Health Union".[35]

This would give rise to new problems. There is the risk of an ever-increasing budget. If the fund is not subject to stringent criteria, there will be the moral hazard risk that Member States take advantage of such a fund and do not resolve issues of shortages that are not caused by parallel trade but by inefficiencies or corruption at national level. As with any kind of funding, there is a risk of fraud. Furthermore, the money that is spent on healthcare cannot be spent on other health policy issues as envisaged under "EU4Health". With more funding for healthcare there is also a risk that it will constitute the next step towards more centralization of healthcare policy at EU level, which may run counter to the preference of Member States to keep healthcare policy at national level.

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32 European Commission (2020), "Pharmaceutical Strategy for Europe", p. 17.
33 The Economist Intelligence Unit (2017), "Cancer Medicines shortages in Europe: Policy Recommendation to prevent and manage shortages", p. 13.
34 European Commission (2021), "EU4Health 2021-2027 – a vision for a healthier European Union".
35 European Commission (2021), "Pharmaceutical Strategy for Europe", p. 2.

In order to at least reduce these risks, the following restrictions would be essential: The fund would have to be strictly limited in size and only targeted at real emergency situations for which strict criteria would not only have to be established but also be applied. Instead of using additional money, the EU should finance such a fund with resources for health provided by the new budget 2021 – 2027 and NextGenerationEU. It may also be possible to shift money within the budget from other consumption expenditures towards a health care fund.

4.3 Unitary Pricing for all Member States

Unitary pricing means that a pharmaceutical company negotiates one price for a specific product that has to be paid everywhere in the EU. This requires the national health systems to delegate the negotiating power to an institution that does the bargaining for them. If all European countries sign up to an EU-wide negotiation, it will comprise almost 25% of global prescription drug revenue for an average drug.[36] The EU's first objective of free movement of pharmaceuticals would be guaranteed.

Also, the incentives for parallel trade would be significantly reduced within the EU. Nevertheless, shortages in low-income countries may still occur but now for a different reason: The unitary price would be an average of nationally negotiated prices. It might therefore be too high for a number of national health systems to guarantee reimbursement so the pharmaceuticals will only be available to patients who can afford them. In line with the reduction in parallel trade, the risk of falsified pharmaceuticals may also go down in high-income countries but be higher in low-income countries as smuggling from outside the EU would become a problem. Since prices of pharmaceuticals are published under this approach, there would be a major improvement in transparency of pharmaceutical prices. With just one price in the EU, and limited parallel trade, it would be much easier for pharmaceutical companies to do their cost calculations due to increased predictability of sales prices.

In addition to these effects, there are other consequences of a unitary pricing system: It would increase bargaining power when negotiating with pharmaceutical companies. This would mainly benefit smaller EU Member States. Unitary pricing would, however, call for some kind of redistribution among Member States in order for the average price to be accepted even in the poorer ones. Furthermore, it would have to be decided who is in charge of the price negotiations. The EU Commission or the EMA would lack the incentive to negotiate lower prices because it is not their money that is at stake. It would therefore have to be an institution established and controlled by the national health systems and health insurers.

This might prove to be impossible, due to the fundamentally different approaches of these systems, unless national healthcare regulation in the areas concerned is streamlined or even harmonized. This may apply in particular to different reimbursement systems, which not only differ between national health care systems, but even within them, e.g., regarding in-patients and out-patients, primary care patients and hospital-based treatments. Additionally, an EU-wide price agreement would be difficult to achieve for many pharmaceuticals because preferences vary widely across Europe. Centralized pricing negotiations would also eliminate competition among national health insurers, who, as in Germany, are eager to negotiate favourable discount contracts for their clients in order to keep their insurance premiums low. Though central European price negotiations are a theoretical option, a lot of

[36] ZS (2021) "European drug pricing alliances: Force or farce?"

work is needed to achieve a common European approach for the very diverse national health care systems.

5 Conclusion

Parallel trade is a form of arbitrage: A product, sold by the manufacturer in country X at a lower price than in country Y, is bought by a dealer in country X and sold in country Y. It is particularly relevant for pharmaceuticals in the internal market of the EU.

Parallel trade may lead to pharmaceutical shortages in low-price countries and increase the potential risk of falsified pharmaceuticals. It adds to the non-transparency of pricing of pharmaceuticals and can lead to calculation problems for manufacturers.

The significance of parallel trade differs among EU countries. It is negligible in France and Italy while in Germany, 8.5% of the pharmaceuticals sold are traded in parallel, and in Denmark the figure is 26.2%.

The EU's position on the parallel trade in pharmaceuticals is contradictory: It calls for both the free movement of medicines in the internal market and equal access to pharmaceuticals for all EU citizens.

There are three basic options for addressing parallel trade: the exclusion of pharmaceuticals from the internal market rules, open redistribution among the national health systems by a subsidisation fund, and a unitary price that has to be paid everywhere in the EU.

None of these options eliminates the problems caused by parallel trade, without raising other issues. A political debate is needed on what trade-offs should be made.

Centrum für Europäische Politik
FREIBURG | BERLIN

Authors:

Nathalja Nolen, LL.M, MSc, M.A., Policy Analyst
nolen@cep.eu

Dr. Stephan Balling, Scientific Advisor
balling@cep.eu

Centrum für Europäische Politik FREIBURG | BERLIN
Kaiser-Joseph-Straße 266 | D-79098 Freiburg
Schiffbauerdamm 40 Raum 4315 | D-10117 Berlin
Tel. + 49 761 38693-0

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