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Ex Post Assessment of European Competition Policy:

The Pharmaceutical Parallel Trade Cases

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1. Introduction

This working paper presents an ex-post assessment of the enforcement of competition law regarding restrictions targeting parallel trade of pharmaceuticals in the European Union (EU). Parallel trade is the activity of re-selling pharmaceuticals in another country without the express consent of the company who holds the marketing authorisation. This trading activity is driven by the price difference that exists between countries. Specifically, traders purchase the medicine at a low price in one country to resell it at a higher price in another country. In many developed countries parallel imports of pharmaceuticals are illegal. For example, pharmaceuticals sold abroad cannot legally be imported in the US where prices tend to be higher than the rest of the world. However, within the European Economic Area (EEA), once the holder of the marketing authorisation for a medicine (either granted centrally by the European Medicines Agency (EMA) or by a national competent authority) supplies that product in one Member State, this medicine can be resold in other Member States without its authorisation.

In a number of cases in the first decade of the 21st century, the Court of Justice of the European Union (CJEU) has considered whether the use of trade restrictions by the holder of the marketing authorisation to prevent distributors from engaging in parallel trade within the EEA, infringes EU competition rules (in particular what are now Article 101 and 102 TFEU). These rules have the objective of facilitating the creation of the EU Single Market and of promoting consumer welfare through the prevention of inefficient business practices. The CJEU held that restrictions of parallel trade may breach the EU competition rules in certain circumstances.

This paper starts with a brief description of the characteristics of the pharmaceutical sector, in particular as regards distribution and pricing (section 2) before discussing the role of the Single Market imperative in EU law (section 3). Section 4 contains a succinct description of the case law of the CJEU on parallel trade in pharmaceuticals. Section 5 presents the ex-post assessment of this case law, in particular the extent to which the judgements have affected the development of the parallel trade of pharmaceuticals in the Single Market, and further the effects of parallel imports on prices and innovation. Section 6 concludes.

2. Background to the pharmaceutical sector

a. Pharmaceutical distribution

The distribution and sale of pharmaceuticals is heavily regulated, principally at a national but to some extent also at a European level. This regulation has several, sometimes conflicting, goals, including: ensuring the safety and quality of drugs, controlling the health care expenditure on drugs while guaranteeing access to patients, and encouraging innovation.[1]

Medicinal products reach consumers essentially in two ways: either as part of a treatment in a hospital, or as a product sold in community pharmacies (or, in some EU Member States, in other retail outlets). Some pharmaceutical products can be freely purchased by consumers in community pharmacies (over-the-counter (OTC)). However, most pharmaceutical products sold in pharmacies can only be purchased if a medical doctor has provided the consumer with a medical prescription for that drug.[2] In the case of such prescription-only medication, just like for pharmaceuticals administered in hospital, the decision to procure a drug is not really made by the patient, but rather by the physician. There are differences between Member States as to which drugs are available in community pharmacies and in hospitals, as well as to which drugs are OTC and prescription only.

It is rare for manufacturers of pharmaceuticals to supply community pharmacies directly. In all EU Member States, wholesalers supply a full line of products from multiple manufacturers to pharmacies. The distribution channel is vertically integrated in some countries, where wholesale activities are run by large pharmacies, and in other countries, there are independent players at each step of the distribution chain. Hospital pharmacies generally tender supply contracts to pharmaceutical manufacturers and wholesalers, often through purchasing alliances.

b. Pharmaceutical pricing

As indicated above, most pharmaceutical products are administered based on the decision of a doctor, who is not paying for the product. Furthermore, although consumers usually pay for OTC drugs, all or a large extent of the cost of prescription drugs is usually covered, depending

[1] See OECD, *Competition and regulatory issues in the pharmaceutical industry* (2000) 21. See also E Mossialos, T Walley and M Mrazek, 'Regulating pharmaceuticals in Europe: an overview' in E Mossialos, M Mrazek and T Wally (eds), *Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality* (Open University Press 2004) 1, 22 who list additional objectives.

[2] Article 71(1) of Directive 2001/83/EC on the Community code relating to medicinal products for human use (2001) OJ L311/67 provides that this is for medicinal products which are (i) likely to present a danger either directly or indirectly, even when used correctly, if utilized without medical supervision, or (ii) are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health, or (iii) contain substances or preparations thereof, the activity and/or adverse reactions of which require further investigation, or (iv) are normally prescribed by a doctor to be administered parenterally.

on the Member State, by (private or public) health insurance. In those circumstances, final consumer demand for pharmaceuticals tends to be inelastic.[3]

To limit the burden that this would pose on health insurers, Member States use regulatory intervention, which comes in a variety of ways. These include demand-side tools which aim to reduce the consumption of reimbursed drugs, such as excluding certain drugs from formularies of approved and reimbursed drugs (e.g. where cheaper equivalents are available), and requiring a co-payment from consumers (i.e. where only part of the price of the drug is reimbursed). Some EU Member States also incentivise or require physicians to limit the total amount of drugs (in monetary terms) they prescribe, and incentivise or require physicians and/or pharmacists to prescribe or dispense cheaper (e.g. generic) variants of drugs if these are available.

One important tool available to limit expenditure on pharmaceuticals is price control. In that case the (public) insurer usually negotiates a maximum price or a maximum profit margin with the manufacturer, or limits the reimbursement provided to the consumer (reference pricing). EU law merely requires that the way prices are set is (to some extent) transparent,[4] but otherwise leaves Member States a free choice of techniques to do so. As a result, and despite the incorporation of international price comparisons in many national price setting mechanisms, there are significant price differences between different EU Member States.

Some EU Member States do not merely regulate drug prices but also the margins which pharmacies and wholesalers can earn on pharmaceutical sales (or their profits more generally), thereby diminishing their ability and incentive to negotiate purchase prices with manufacturers. There are nevertheless schemes in some Member States to incentivise wholesalers and pharmacies to negotiate rebates on their purchase prices, for example by paying pharmacies (partially) per item dispensed. Cheaper parallel imports are also more attractive under such schemes than in situations where the margin of the pharmacy increases with its purchase price. In many Member States, pharmacists are required to dispense cheaper versions of drugs if these are available, including from foreign sources. In Germany, pharmacies are furthermore required by law to dispense drugs that come from parallel imports until a certain target saving has been achieved.[5] Insurers may in turn claw back some of the extra profit pharmacies earn this way.

[3] OECD, *Competition and regulatory issues in the pharmaceutical industry* (2000) 40; B Durand, 'Competition law and pharma: an economic perspective' in P Figueroa and A Guerrero Perez (eds), *EU law of competition and trade in the pharmaceutical sector* (Edward Elgar 2019) 1, 6.

[4] Pursuant to Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (1989) OJ L40/8.

[5] D Panteli, R Busse et al (eds), *Pharmaceutical regulation in 15 European countries : Review* (European Observatory on Health Systems and Policies 2016) 59 and 65.

3. EU Single Market imperative

a. General description

The European Economic Community was created to establish a common market, including through the abolition of restrictions on the free movement of goods between EU Member States.[6] This entailed the elimination of tariffs between Member States as well as the removal of any quantitative restrictions on imports and exports and measures having equivalent effect, unless such restrictions are justified by public interest concerns.[7]

b. Restrictions on parallel trade imposed by Member States and IP rights

In the pursuit of this objective, European law requires Member States to abolish any restrictions on the parallel trade of pharmaceutical products, except if such restrictions are justified by public interest concerns such the health and life of humans. The CJEU has multiple times found that restrictions on the import of pharmaceuticals fail to be justified in this sense,[8] but the prohibition of exports is similarly problematic.

The requirement that drugs marketed in EU Member States receive a marketing authorisation is as such not a restriction of trade. Indeed, EU law requires that drugs benefit from a marketing authorisation before they are marketed.[9] However, once such an authorisation has been granted, national legislation cannot prevent parallel traders from importing the product in question.[10] The European courts have also required Member States to grant market authorisations to parallel importers under a proportionally simplified procedure when the information necessary for the purposes of protecting public health is already available to the competent authorities of the Member State of destination, and the Commission has even issued guidelines to that effect.[11] In some circumstances, parallel import licences must be maintained, even after the holder of the original market authorisation requests the withdrawal of the authorisation.[12]

The EU has furthermore taken positive harmonisation steps through the adoption of common rules regarding the adoption of marketing authorisations (a decentralised but uniform marketing authorisation system) as well as a centralised marketing authorisation procedure for European market authorisations processed by the EMA.[13]

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[6] See in particular Articles 2 and 3 of the Treaty establishing the European Economic Community.
[7] See Article 30ff EEC, currently Article 34ff TFEU.
[8] See, for example, C-215/87 *Schumacher v Hauptzollamt Frankfurt am Main-Ost* ECLI:EU:C:1989:111; C-62/90 *Commission v Germany* ECLI:EU:C:1992:169; and C-387/18 *Delfarma* ECLI:EU:C:2019:556.
[9] See already Article 3 of Directive 65/65/EEC on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products (1965) OJ 22/369 and currently Article 5(1) of Directive 2001/83/EC on the Community code relating to medicinal products for human use (2001) OJ L311/67.
[10] C-104/75 *De Peijper* ECLI:EU:C:1976:67.
[11] Commission communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted (COM(2003) 839 final)
[12] C-172/00 *Ferring* ECLI:EU:C:2002:474.
[13] See Articles 6-39 of Directive 2001/83 on the Community code relating to medicinal products for human use (2001) OJ L311/67 and Regulation 726/2004 laying down Community procedures for the authorisation and

Parallel imports are further aided by the application of the principle of exhaustion of intellectual property (IP) rights across the EU. The CJEU indeed established that a holder of a patent or trademark exhausts his rights across the whole of the EU by voluntarily placing a product on the market in any one of the Member States.[14] Provided certain conditions are met, IP rights therefore cannot prevent the commercialisation of a drug that is sold in one Member State, also in other Member States.[15]

Beyond marketing authorisations, Member States regulate pharmaceutical sales in other ways. For example, Member States in the past imposed various packaging requirements on drugs sold in their territory: this was allowed to the extent that such requirements were essential to protect human health.[16] Member States are also allowed to grant pharmacies a monopoly to sell pharmaceutical products[17] and to regulate other aspects of the sale of pharmaceuticals, if this does not disadvantage foreign products.[18]

The institution of price control mechanisms for pharmaceuticals is in principle a prerogative of the Member States. However, the CJEU has taken issue with features of price control systems which restrict trade between Member States, such as a differentiated system of price controls for imported pharmaceuticals as opposed to medicines produced domestically.[19] Also the extension of price controls for prescription-only drugs to products procured by consumers from mail-order pharmacies in other Member States is considered to be an unjustified restriction on the free movement of goods.[20]

c. Interaction with public health policy

While European law only allows restrictions on the free movement of pharmaceuticals if these are required to protect the health and life of humans, public health policies also pursue other objectives such as guaranteeing access to medicines while controlling health care expenditures and encouraging innovation.

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supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (2004) OJ L136/1.

[14] C-15/74 *Centrafarm BV and Others v Sterling Drug* ECLI:EU:C:1974:114 and C-16/74 *Centrafarm BV and Others v Winthorp BV* ECLI:EU:C:1974:115. In the case of trademarks, the principle is currently included in Article 15 of Directive 2015/2436 to approximate the laws of the Member States relating to trade marks (2015) OJ L336/1.

[15] In the case of repackaging, these conditions include that the repackaging must be necessary, that the new packaging clearly states who repackaged the product and the name of the manufacturer, that the repackaged product is not liable to damage the reputation of the trade mark and of its owner, and that the importer gives notice to the trade mark owner before the repackaged product is put on sale. See Case C-436/93 *Bristol-Myers Squibb v Paranova* ECLI:EU:C:1996:282.

[16] See Article 6 and 7 of Directive 75/319/EEC on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products (1975) OJ L147/13. These requirements are currently mainly regulated through European law in Directive 2001/83/EC on the Community code relating to medicinal products for human use (2001) OJ L311/67.

[17] C-369/88 *Delattre* ECLI:EU:C:1991:137.

[18] C-322/01 *Deutscher Apothekerverband* ECLI:EU:C:2003:664.

[19] C-181/82 *Roussel* ECLI:EU:C:1983:352.

[20] C-148/15 *Deutsche Parkinson Vereinigung* ECLI:EU:C:2016:776.

The European Commission has argued that the creation of a Single Market in pharmaceuticals would also facilitate the achievement of these other policy objectives. The divergences between regulatory regimes in different Member States may create delays in the marketing of drugs, while a Single Market may encourage R&D investments in Europe.[21]

On the other hand, the effects of policy on health care mainly arise at a national level. In this respect, different Member States make different choices and are confronted with different realities, in terms of what are acceptable health care costs both for their public finances and their respective population. This is reflected in the different regulatory requirements individual Member States have established, including for pricing and reimbursement.

The free movement of pharmaceuticals across EU Member States may therefore both facilitate and obstruct public health policies.

d. The Single Market objective, economic efficiency, and the parallel trade of pharmaceuticals

In the middle of the 1980s, when the European Commission published its *White Paper on Completing the Internal Market,*[22] it noted the clear economic benefits that an internal market brings: "The creation of a true European internal market will, on the one hand, suppress a series of constraints that today prevent enterprises from being as efficient as they could be and from employing their resources to the full, and, on the other hand, establish a more competitive environment which will incite them to exploit new opportunities."[23]

By creating a free trade area, the Single Market objective seeks to increase the prosperity of the EU by allowing consumers to buy more, better-quality products at lower cost. In particular, free trade within the Single Market is expected to improve economic efficiency, notably by shifting resources to more productive uses, and thereby fuelling economic growth. Free trade also imposes competitive discipline on firms, given them further incentives to minimise costs and keep prices low.

In principle, market integration could deliver a more efficient allocation of resources, more quantity produced and sold, and low prices. However, when firms set different prices in different countries, this can improve economic efficiency too. This is the case when differences in demand across countries are large, such that so-called "price discrimination" enables firms to sell more products than they would otherwise. Indeed, such a pricing policy allows consumers in low-price countries to acquire the product in question, whilst if the price were the same everywhere, these would not be served. Malueg and Schwartz (1994) formalises this argument.[24] Naturally, this pricing policy can work only if there is no arbitrage.

[21] See, in particular, the Commission Communication on the single market in pharmaceuticals (COM(1998) 588 final) and the Commission Communication on safe, innovative and accessible medicines: a renewed vision for the pharmaceutical sector (COM(2008) 666 final).

[22] White Paper from the Commission to the European Council 'Completing the internal market' COM (85) 310 final.

[23] European Commission, 'The economics of 1992' (1988) 35 European Economy 17.

[24] D Malueg and M Schwartz, 'Parallel imports, Demand Dispersion and International Price Discrimination' (1994) Journal of International Economics 37.

That is, the goods sold in the low-price countries cannot be resold in the high-high price countries. In other words, restricting parallel trade is required to achieve this type of efficiency gains.

Given the importance of R&D investments and innovation in the pharmaceutical sector, the question of parallel trade and market integration must also be examined with this aspect in mind. Whilst low medicine prices generate cost savings for national health insurance and contribute to maintain affordable health care, at the same time, they reduce the incentives of pharmaceutical companies to invest in R&D, potentially limiting the pace of innovation. Because the industry is heavily regulated, each Member State can set the cursor depending on its preference, either to favour innovation or to select low price. However, as shown by Rey (2003), in theory parallel trade can challenge the ability of Member States to make such a choice, and result in inefficient outcomes.

4. Historical development of the case law

a. Article 101 TFEU

In line with the Single Market imperative discussed above, agreements which restrict parallel trade have been found to amount to a restriction of competition in the sense of (what is now) Article 101 TFEU since the 1970s. In particular, the CJEU has held that "by its very nature, a clause prohibiting exports constitutes a restriction on competition".[25] This principle was also applied in the pharmaceutical sector.[26]

(i) *Bayer Adalat*

In 2000, the Court of First Instance (CFI) nevertheless created an opening for restrictions of parallel imports imposed by suppliers of pharmaceutical products in its *Bayer (Adalat)* judgment. This judgment concerned a Commission decision of 1996 which had found that Bayer had infringed what is now Article 101 TFEU by reducing supplies to the French and Spanish distributors of its Adalat drug to prevent them from exporting to the UK, where prices were higher. Bayer did not inform the French and Spanish distributors that the volume reduction was due to concerns about parallel trade (it cited "stock shortages") but the distributors nevertheless guessed the real motives and reduced their orders, while at the same time increasing purchases through other wholesalers, in order to continue exporting.[27]

In its 2000 judgment, the CFI annulled the Commission decision on the basis that it was not established that there was an "agreement" in the sense of Article 101 TFEU between Bayer and its distributors. According to the CFI, there was no evidence of acquiescence of the distributors with Bayer's policy of reducing exports: on the contrary, the fact that the distributors sought alternative sources of supply showed that they did not agree with Bayer's attempts to restrict exports.[28] The CFI's judgment was subsequently confirmed by the CJEU.[29]

Some *dicta* of the CFI suggested that its ruling was informed by the specific characteristics of the pharmaceutical markets,[30] but the principle that acquiescence by distributors cannot simply be presumed was confirmed in later case law in other sectors.[31] This case law therefore allowed suppliers of pharmaceuticals which were not dominant to unilaterally limit supplies to wholesalers. It did not, however, permit them to agree with their distributors to limit exports.

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[25] Case C-19/77 *Miller International Schallplatten GmbH v Commission* ECLI:EU:C:1978:19, para 7.
[26] See case C-277/87 *Sandoz Prodotti Farmaceutici v Commission* ECLI:EU:C:1990:6. Note that only a summary of this judgment was published.
[27] Commission decision of 10 January 1996 in case 34.279 *Adalat*.
[28] Case T-14/96 *Bayer v Commission* ECLI:EU:T:2000:242.
[29] Joined cases C-2/01 and 3/01 *BAI v Bayer and Commission* ECLI:EU:C:2004:2.
[30] See case T-14/96 *Bayer v Commission* ECLI:EU:T:2000:242, paras 179-181. See also P Rey and JS Venit, 'Parallel Trade and Pharmaceuticals: A Policy in Search of Itself' (2004) 29 European Law Review 153 and U Wickihalder, 'The distinction between an "agreement" within the meaning of Article 81(1) of the EC treaty and unilateral conduct' (2006) 2 European Competition Journal 87.
[31] See in particular case T-368/00 *General Motors Nederland and Open Nederland v Commission* ECLI:EU:T:2003:275, confirmed in case C-74/04 P *Commission v Volkswagen* ECLI:EU:C:2006:460.

(ii) *Glaxo Spain* (object infringement)

The CFI created another opening for possible restrictions of parallel trade in pharmaceuticals in 2006, when it ruled in *Glaxo Spain* that a restriction of parallel trade in pharmaceuticals is not necessarily a restriction by object and considered that the Commission had not correctly assessed the possible justification for such a restriction under what is now Article 101(3) TFEU.

In this case, GlaxoSmithKline (GSK) had notified[32] the Commission of proposed contracts with its Spanish wholesalers which contained a clause providing for differentiated pricing for medicinal products financed by Spanish social security funds and subsequently marketed in Spain, on the one hand, and other medicinal products, on the other hand. In 2001, the Commission decided that this dual pricing system amounted to a restriction of competition in the sense of Article 101 TFEU both by object and effect.[33]

Following an application for annulment by GSK, the CFI upheld the Commission's finding of a restriction by effect but annulled the qualification of a restriction by object. The CFI considered that, while restrictions of parallel trade must "in principle" be regarded as having as their object the prevention of competition, this was only in so far as such restrictions can be presumed to deprive the "final consumer" of the benefit of competition. The "special and essential characteristics" of the pharmaceutical sector, however, imply that the benefits of parallel trade may to a large extent be kept by parallel traders.[34] As a consequence, the prices of medicines "are to a large extent shielded from the free play of supply and demand" and "it cannot be taken for granted at the outset that parallel trade tends to reduce those prices and thus to increase the welfare of final consumers."[35]

However, the CJEU did not agree with the CFI's analysis and instead adhered more closely to the Single Market imperative. It held that the principle that restrictions of parallel trade have as their object the restriction of competition also applies to the pharmaceutical sector. According to the CJEU, such a finding is not dependent on the requirement that final consumers be deprived of the advantages of effective competition. The differentiated pricing used by GSK therefore amounted to a restriction of competition by object.[36]

(iii) *Glaxo Spain* (Article 101(3) TFEU)

As indicated above, the CFI was also critical of the Commission's assessment of the application of paragraph 3 of what is now Article 101 TFEU. GSK had raised a number of arguments in this

[32] Pursuant to the notification procedure which existed under Regulation 17/62: first regulation implementing Articles 85 and 86 of the Treaty [1962] OJ 13/204, but which was abolished by Regulation 1/2003 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty [2003] OJ L1/1.
[33] Commission decision of 8 May 2001 in cases 36.957 Glaxo Welcome (notification); 36.997 Aseprofar and Edifar (complaint); 37.121 Spain Pharma (complaint); 37.138 BAI (complaint) and 37.380 EAEPC (complaint), recitals 115-143.
[34] These characteristics include the fact that the prices for pharmaceuticals are fixed by national authorities (although the Spanish legislation did not impose a system of differentiated prices), that the latter also bear the essential part of the cost of the medicines and that there is little harmonisation in this field.
[35] Case T-168/01 *GlaxoSmithKline Services v Commission* ECLI:EU:T:2006:265, paras 114-147.
[36] Joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline Services and Others v Commission and Others* ECLI:EU:C:2009:610, paras 54-67.

respect but the focus of the CFI was on GSK's reasoning that restricting parallel trade contributed to technical progress because it stopped the erosion of profits caused by parallel trade, which in turn reduced the funds pharmaceutical companies had available for R&D. The Commission had dismissed this argument in its decision on the basis (i) that there was no guarantee that any additional profits obtained by these restrictions would actually be invested in R&D (rather than simply being retained as additional profits) and (ii) that the impact of parallel trade on profits was in any event small.[37]

The CFI considered that the Commission had not properly examined all the arguments GSK had made in this respect and in particular (i) that the Commission's analysis of the link between parallel trade and R&D expenditure was not "rigorous" and "thorough" enough and (ii) that the Commission did not seriously examine whether the losses as a result of parallel trade were significant.[38] Since the remainder of the Commission's argumentation on the application of what is now Article 101(3) TFEU rested on the conclusion that the restrictions did not provide a gain in efficiency, the CFI concluded that the Commission's decision needed to be annulled on this basis as well.

In its appeal to the CJEU, the Commission argued that the CFI had misallocated the burden of proof for the establishment of the conditions of Article 101(3) TFEU, had distorted the arguments made by the parties in this respect, and had exceeded the limits of its judicial review. However, the CJEU dismissed all these arguments.[39]

(iv) *EAEPC v Commission*

Following the CJEU's judgment in 2009, GSK withdrew its notification to the Commission of the contracts with the Spanish wholesalers. One of the complainants in the case, the European Association of Euro-Pharmaceutical Companies (EAEPC), requested the Commission to nevertheless adopt a new decision on the pricing practices of GSK in Spain. By a decision in 2014, the Commission rejected EAEPC's complaint on the basis that GSK was not using the dual pricing system anymore, that there were no persistent effects of the dual pricing system practiced by GSK in Spain more than a decade before, and that national competition authorities and courts were in any event well placed to deal with EAEPC's complaints, such that the Commission did not need to prioritize it.[40]

EAEPC brought an application for annulment before the General Court against this Commission decision. The General Court rejected that application, holding that the Commission was not required to adopt a new decision following the withdrawal of GSK's notification and that it did not make a manifest error of assessment when concluding that the

[37] Commission decision of 8 May 2001 in cases 36.957 *Glaxo Wellcome (notification)*; 36.997 *Aseprofar and Edifar (complaint)*; 37.121 *Spain Pharma (complaint)*; 37.138 *BAI (complaint)* and 37.380 *EAEPC (complaint)*, recitals 154-169.

[38] Case T-168/01 *GlaxoSmithKline Services v Commission* ECLI:EU:T:2006:265, paras 247-303.

[39] Joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline Services and Others v Commission and Others* ECLI:EU:C:2009:610, paras 68-168.

[40] Commission decision of 27 May 2014 in case 36.957 *Glaxo Wellcome (complaint)*.

union interest did not require further action on its part.[41] No appeal was brought against this judgment to the CJEU.

b. Article 102 TFEU

The CJEU has for a long time considered that the creation of barriers to parallel trade can constitute an abuse of dominance in the sense of Article 102 TFEU.[42] The question of whether this was also the case for trade in pharmaceuticals products did not reach the CJEU before the *Glaxo Greece* case.

This case arose because the exports by pharmaceutical wholesalers in Greece had led to shortages of certain medicines in the Greek market. GSK had therefore started distributing its products itself and, after the conditions on the Greek market stabilized, it limited the quantities it supplied to Greek wholesalers. In an interim judgment, the Hellenic Competition Commission considered that this amounted to an abuse of dominance and requested a preliminary ruling from the CJEU, but that request was rejected as inadmissible.[43] However, in the parallel cases before the civil courts, the Athens Court of Appeal referred the same questions to the CJEU.

In a Grand Chamber judgment, the CJEU considered that intrabrand competition may be the only form of competition for patent protected pharmaceuticals and that therefore it is not permissible for dominant pharmaceutical undertakings to stop all parallel trade. On the other hand, a dominant undertaking should be allowed to counter in a reasonable and proportionate way the threat to its own commercial interests potentially posed by significant orders that are essentially destined for parallel exports. The Court, therefore, considered that a dominant undertaking abuses its position if it refuses to meet "ordinary orders" from its customers but, it seems, not if it refuses to meet orders that are out of the ordinary. What "ordinary" means, the Court left for the national court to decide "in the light of both the size of those orders in relation to the requirements of the market […] and the previous business relations between that undertaking and the wholesalers concerned."[44]

[41] Case T-574/14 *EAEPC v Commission* ECLI:EU:T:2018:605. The General Court nevertheless also ruled that the Commission had "mischaracterized" its 2001 decision as being "null and void". The General Court clarified that the CJEU had in 2009 upheld the Commission's conclusion that dual pricing constituted a restriction of competition by object, and had only annulled the decision in relation to the Commission's insufficient assessment of GSK's efficiency defence under Article 101(3) TFEU.

[42] See, for example, C-27/76 *United Brands v Commission* ECLI:EU:C:1978:22 and C-226/84 *British Leyland v Commission* ECLI:EU:C:1986:421.

[43] Case C-53/03 *Syfait and Others* ECLI:EU:C:2005:333.

[44] Joined cases C-468/06 to C-478/06 *Sot. Lélos kai Sia and Others* ECLI:EU:C:2008:504, paras 33-77. The final ruling on the merits of this case in Greece is discussed below.

5. Ex post assessment

As indicated above, the most significant developments in the enforcement of the EU competition rules on the parallel trade in pharmaceuticals are the CJEU judgments in *Glaxo Spain*[45] and *Glaxo Greece*.[46] In the former, the CJEU held that restrictions of parallel trade, such as dual pricing, have as their object the restriction of competition, but that such restrictions may be justified under Article 101(3) TFEU. In *Glaxo Greece*, the CJEU held that a dominant undertaking abuses its position if it refuses to meet orders from wholesalers that are "ordinary" in the light of both the size of those orders in relation to the requirements of the (national) market and the previous business relations between that undertaking and the wholesalers concerned, but not if it refuses to meet orders that are out of the ordinary. As is apparent from this description, the case law neither entirely bans restrictions of parallel trade in pharmaceuticals, nor always permits such restrictions.

In this section, we aim to assess the extent to which these judgments have had an effect on parallel trade in pharmaceuticals in recent years. Unfortunately, the lack of detailed data on the volume and evolution of parallel trade over time prevents us from drawing any conclusions on the causal effects of judgements on the parallel trade of medicines in the EU. In particular, our assessment is somewhat limited by the lack of available data on quantity sold. For instance, to determine whether progress has been made towards the market integration objective, we consider the effect of parallel trade on prices. However, we have no information on whether parallel trade has caused an increase in quantity sold within the EEA, which is relevant to determine whether these activities have delivered efficiency gains.

That said, our analysis provides some evidence regarding the importance of parallel imports in the European pharmaceutical market. Our assessment further considers evidence on the impact of parallel trade on the price of pharmaceutical products and innovation. This analysis also takes into account the role of national regulations and its interplay with parallel trade.

We combine the analysis of publicly available data and a review of recent works on parallel trade, published in economic journals. Specifically, we have relied on the following data sources:

- Information on parallel import licences from the EMA. The EMA, founded in 1995, is a body that evaluates applications for the marketing authorisation of medicines submitted through the so-called centralised procedure for all EU countries. This centralised procedure, however, is not available for all medicines.[47] The EMA also grants parallel distribution licences for medicines approved through the centralised procedure.

[45] Joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline Services and Others v Commission and Others* ECLI:EU:C:2009:610.

[46] Joined cases C-468/06 to C-478/06 *Sot. Lélos kai Sia and Others* ECLI:EU:C:2008:504.

[47] The centralised procedure is compulsory for human medicines containing a new active substance to treat HIV, cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions, and viral diseases. It is also compulsory for medicines derived from biotechnology, advanced-therapy medicines and orphan diseases. The centralised procedure is optional for other medicines.

- Information on parallel import licences from national registries of the three most important destination countries for parallel imports in the EU, namely Denmark, Germany and Sweden.
- Eurostat data on pharmaceutical prices.
- A review of the relevant economic literature concerning the impact of parallel trade on price and on innovation.

In addition, we conducted a survey in September and October 2020 amongst the most significant pharmaceutical originators and wholesalers in the EU. The survey asked the respondents' views on the clarity and suitability of the latest EU antitrust case law on parallel trade in pharmaceuticals, as well as their experience of the existence and extent of parallel trade in pharmaceuticals in the EU and its effects. The response rate of the survey was poor: only a handful of the companies contacted submitted their answer. Amongst the companies that responded, none seemed to have fundamental objections to the case law, although some decried the lack of clarity on certain aspects of the current rules (such as the conditions for the application of Article 101(3) TFEU and the notion of "ordinary orders" in the CJEU's *Glaxo Greece* judgment). Because of the limited response we received, it is not possible to identify any statistically significant patterns in the responses as to the existence and extent of parallel trade, but we have used the responses to interpret and colour some of the data obtained elsewhere.

Our ex-post assessment of the EU case law on parallel trade in pharmaceuticals will start with a discussion of the scale of parallel trade in the EU (section a.) and the evolution of that trade over the years (section b.). Subsequently, we will look at pharmaceutical pricing in the EU and in particular the absence of convergence of pricing and the literature on the effects of parallel trade on pricing (section c.). In section d., we will discuss a number of explanations of the perceived (lack of) effects of parallel trade. The section concludes with a discussion of the literature on the effects of parallel imports on innovation (section e.).

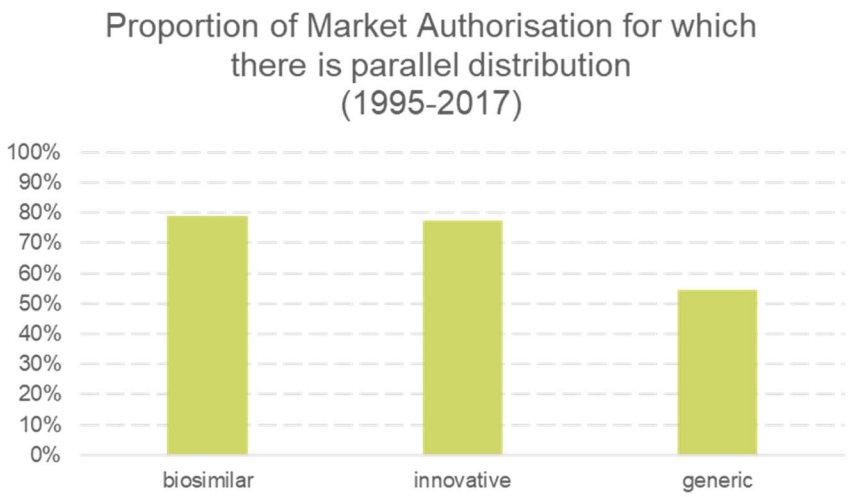
a. The existence of parallel trade in the EEA

The data available to us clearly show that parallel imports of pharmaceutical products continue to be important within the EEA, although the precise volume movements cannot be deduced from the publicly available data which are at our disposal.

The EMA data indicate that for a very large proportion of centrally authorised medicines, a parallel distribution licence was granted. Figure 1 below presents the proportion of medicines authorised between 1995 and 2017 with at least one parallel distribution licence.[48]

[48] We have data until 2020 but excluded the most recent data to alleviate measurement bias. Indeed, a parallel distribution licence can be granted several years after the marketing authorisation.

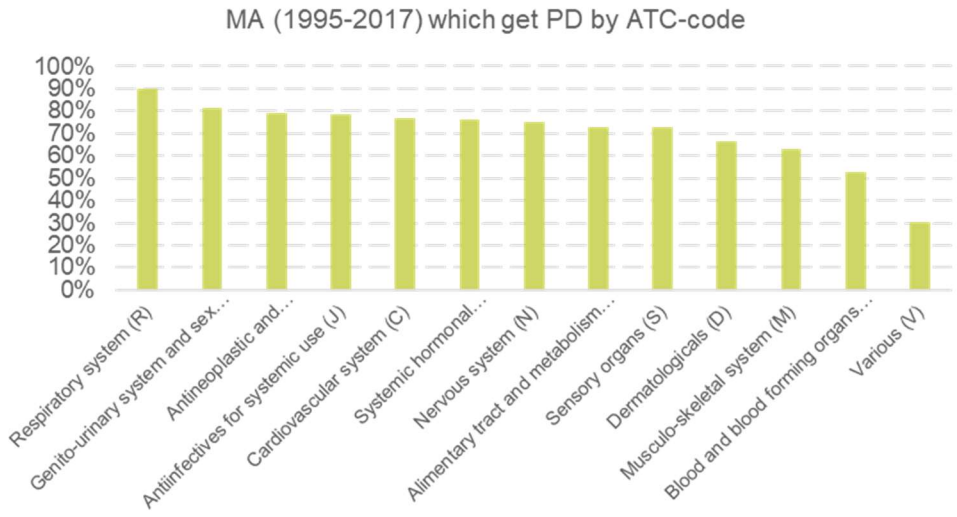
Figure 1



According to the data, for 77% of the innovative medicines approved by the EMA, there is at least one parallel distribution licence. Interestingly that proportion is 79% for bio-similar and 55% for generic. This indicates that parallel distribution does not affect only originator medicines.

Parallel distribution licences affect some categories of medicines more than others. As can be seen in Figure 2 below, the EMA data at the ATC code level show that 90% of medicines in the respiratory system category have at least one licence while that proportion falls to 53% for the blood and blood forming organs category.

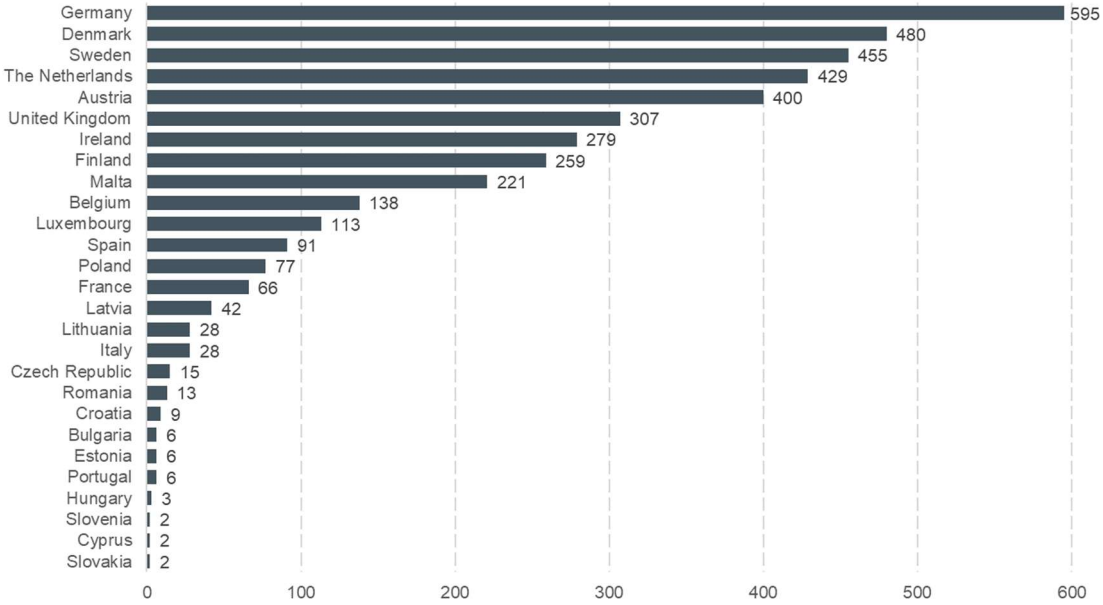
Figure 2



The EMA data also provide a clear picture of the countries that can expect to benefit from parallel imports in the EU, namely the destination countries. Figure 3 below presents the ranking of all EU countries according to the number of medicines that are parallel imported

in each country.[49] There is a distinct group of Northern European countries that represent the major destinations: Germany, Denmark, Sweden, the Netherlands and Austria. In addition, we note that the UK, Ireland, Finland as well as Malta have a large number of medicines that are parallel imported.

Figure 3



It is important to stress that the major destination countries have a regulatory system and rules in place that encourage parallel imports. First, in these countries, pharmaceutical companies have certain freedom in setting prices, which may attract parallel imports if prices are higher than those in other EU Member States where the regulator fixes prices at a lower level. Furthermore, in these destination countries rules have been set up that stimulate price competition and thus parallel imports. As discussed earlier, in Germany, regulation compels pharmacies to source a share of medicines sold from parallel imports. Until July 2019, German pharmacies were obliged to dispense parallel imports when these are 15% or 15 € cheaper than the price of the reference product, until they reach 5% of the total volume. The system has been amended recently but continues to compel pharmacies to use parallel imports until some target savings have been achieved.

In Denmark, pharmacies are required to dispense the cheapest product among available substitutes, unless the patient or the doctor explicitly request otherwise.[50] This provision encourages the sales of generic instead of off-patent products as well as parallel imports. Note that competition from generic and parallel imports is further encouraged by the fact that the patient's co-payment is greater when the more expensive solution is selected.[51]

[49] There is no record of registered parallel import licences for Greece as a destination country.

[50] The pharmacies are obliged to dispense the cheapest product with the same active substance. Pharmaceutical Health Information System (PHIS) Pharma Profile, Denmark, 2011.

[51] Patients who have a supplementary private insurance may have less incentive to accept the substitution if their insurance covers the extra cost.

In Sweden, there is no specific policy encouraging parallel imports. However, regulation encourages substitution to cheaper products, including parallel imports. Since October 2002, Sweden has established the "product of the month", which compels pharmacies to offer the equivalent of the prescribed medicine with the lowest price.[52] The Medical Products Agency decides and publishes the list of interchangeable medicines. That list is updated regularly. Each month the Dental and Pharmaceutical Benefits Agency (TLV) informs which product has the lowest retail price. If the patient refuses the product-of-the-month, she will bear the extra cost.[53]

b. The evolution of parallel imports in the EEA

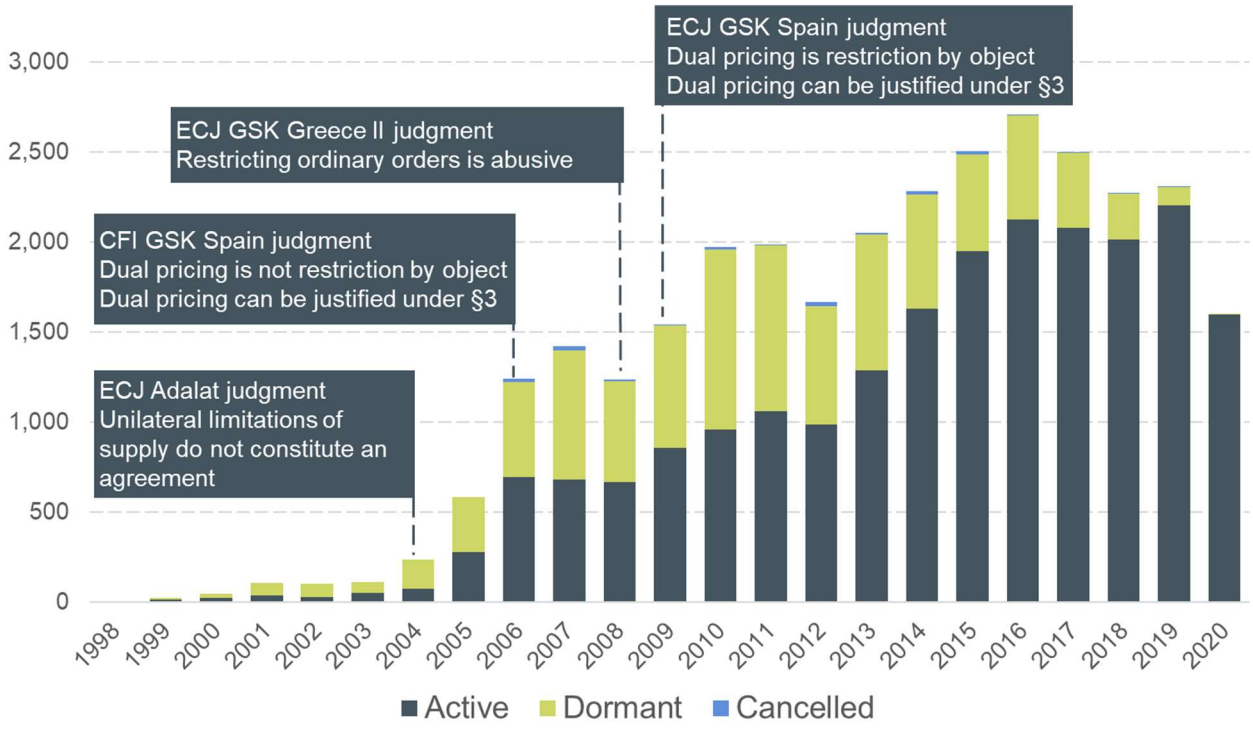
The most obvious way in which the enforcement of the EU competition rules in the area of parallel trade in pharmaceuticals could have an observable effect, would be through the evolution of parallel trade in the EEA. In particular, if the case law described above would have effectively reduced the use of restrictions on parallel trade, this should result in an increase of parallel trade. If, on the other hand, the case law would have become more permissive in respect of restrictions of parallel trade, this should be apparent through a decrease in the volumes of parallel trade.

There is no publicly available information on the trade volume of pharmaceutical products within the EEA. As a proxy, we have considered the annual number of parallel distribution licences granted by the EMA, as reflected in Figure 4 below.

[52] The Medical Products Agency (Läkemedelsverket) defines substitution groups that contains all products that are medically equivalent. Each group contains the originator medicines but also parallel imports and generics for off-patent medicines. Every month, the Dental and Pharmaceutical Benefits Agency (TLV) organises an action for each substitution group, and the winner is the product of the month. The pharmacy is compelled to supply the product of the month, irrespective of whether it was prescribed.

[53] PPRI Pharma Profile, Sweden 2017. WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies.

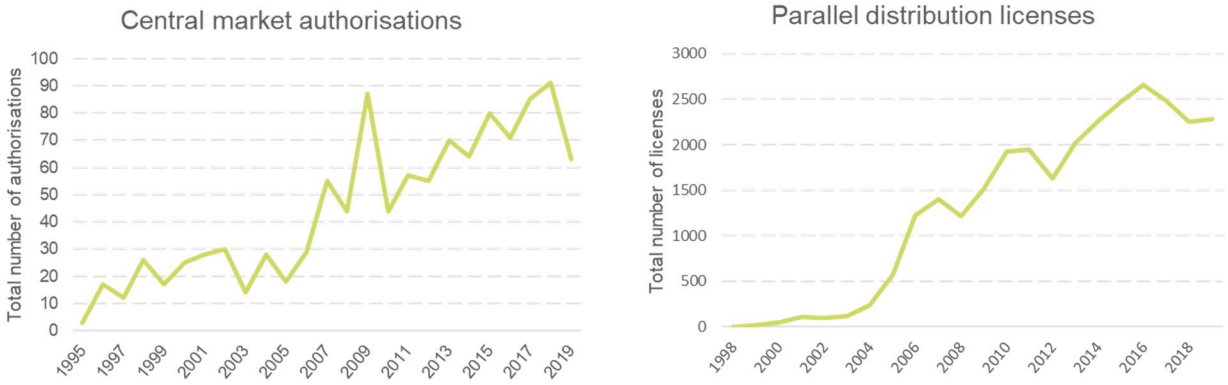
Figure 4



Whilst the data show a growing trend in the number of licences, it is important to note that this accompanies a similar trend in centralised authorisation. When the EMA was established in 1995, it was approving less than 20 medicines in the first couple of years of operations. Still in 2005, ten years later, it granted only 18 authorisations. After 2005, the number of centrally approved medicines started to grow rapidly, however.

The two charts below present separately the total number of market authorisations granted by the EMA each year since 1995 and the total number of parallel trade licences. As can be seen below the number of licences has started to grow sharply after 2004, which corresponds to the time the number of market authorisations has also started to increase significantly.

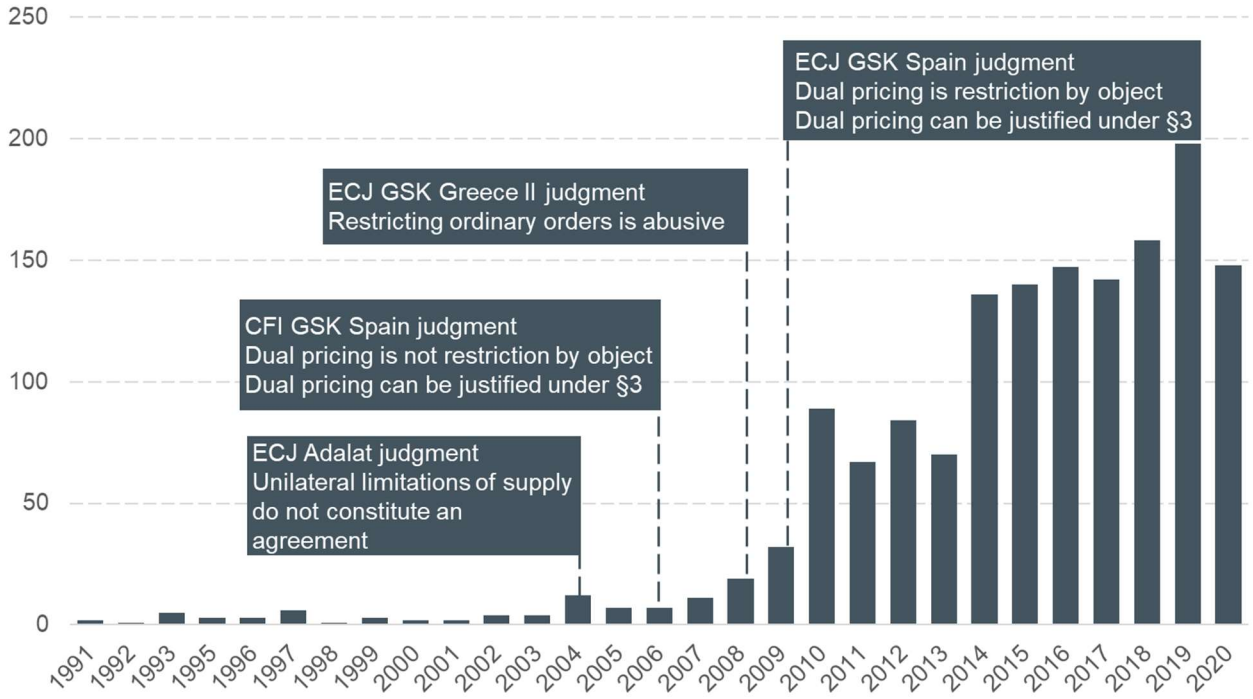
Figure 5: EMA authorisations and licences



Against this background, we do not think it possible to draw any conclusions about the impact of judgments like *Bayer Adalat, Glaxo Greece* or *Glaxo Spain* on the number of parallel distribution licences granted by the EMA.

The next three figures present the number of annual licences for Denmark, Germany and Sweden, based on publicly available data contained in their national medicine registries.

Figure 6: PT licences granted by Denmark



In Denmark, the data shows an apparent increase in the intensity of parallel imports towards the end of the first decade of the 21st century. However, it is important to note that this increase in not recent. Indeed, regulation in Denmark has promoted the growth of parallel imports since the 1990s and expenditures of parallel imported medicines were reported to have increased by 9.5% on average between 2000 and 2009. In 2009, sales of parallel imported products in the so-called primary sector, which concerns treatment and care as well as prevention provided outside the hospital sector, accounted for approximately 8% in volume and 20% in value.[54] Another fact that highlights the importance of parallel imports in that country is that, in 2006, Orifarm, a parallel importer, recorded the largest amount of sales among all pharmaceutical companies.[55]

Figure shows the number of licences for biomedicines in Germany.[56] There does not appear to be a clear trend in this data.

[54] Pharmaceutical Health Information System (PHIS) Pharma Profile, Denmark, 2011.
[55] Ibid, footnote 49.
[56] The data on Human Biomedicines which are parallelly imported since 1995 are provided by the German Paul-Ehrlich-Institut.

Figure 7: PT licences granted by Germany

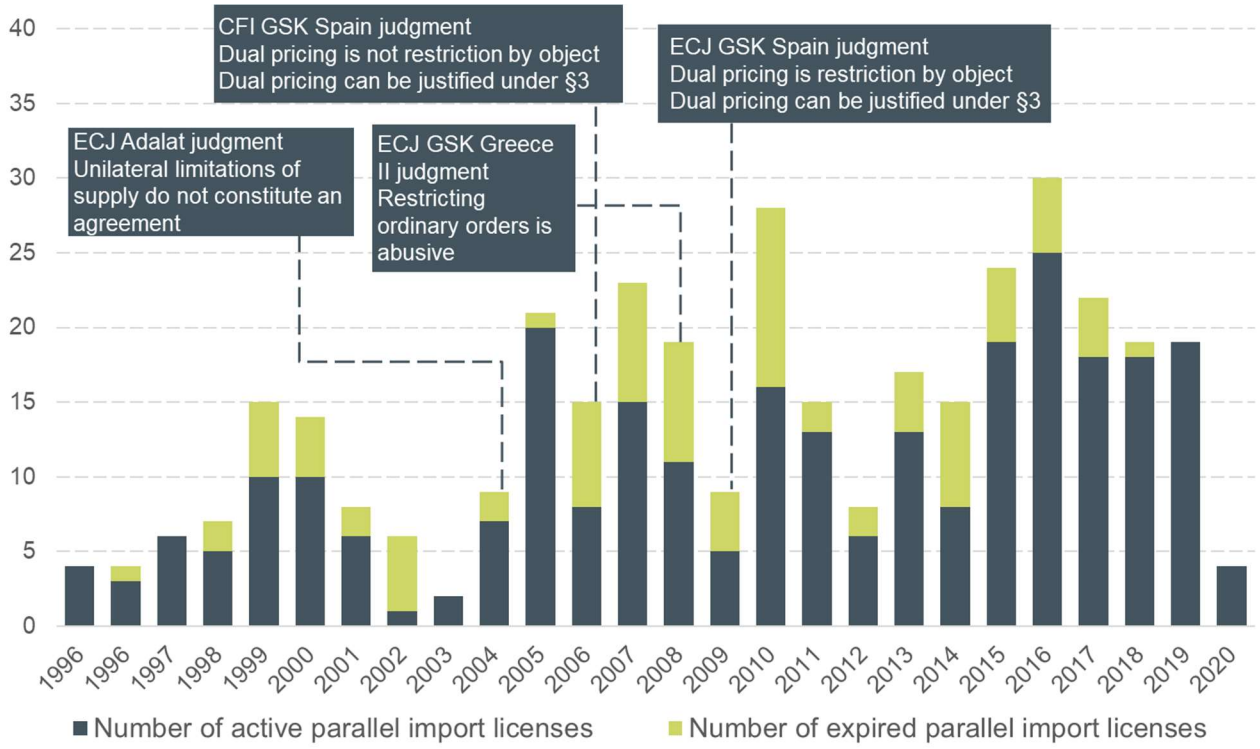
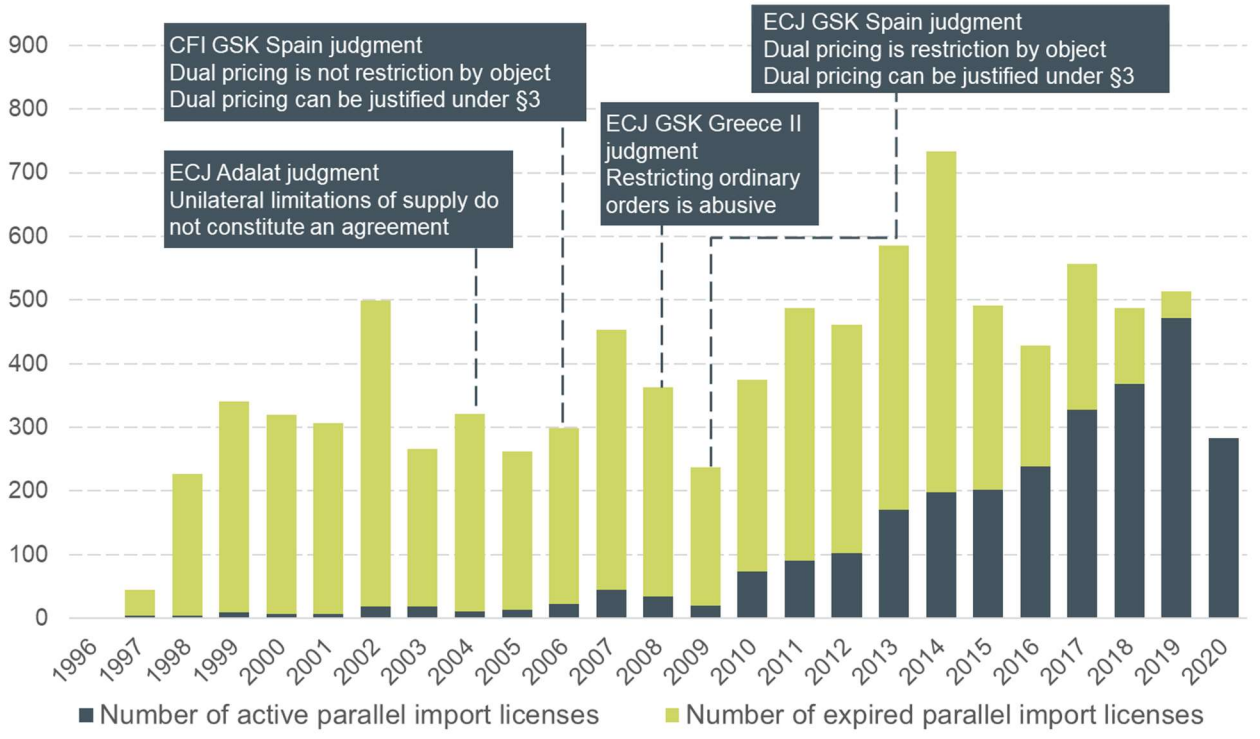


Figure below presents similar data for Sweden. Like for Germany, there is no apparent pattern in the data suggesting that the antitrust case law on restrictions of parallel trade in pharmaceuticals had any effect on parallel imports.

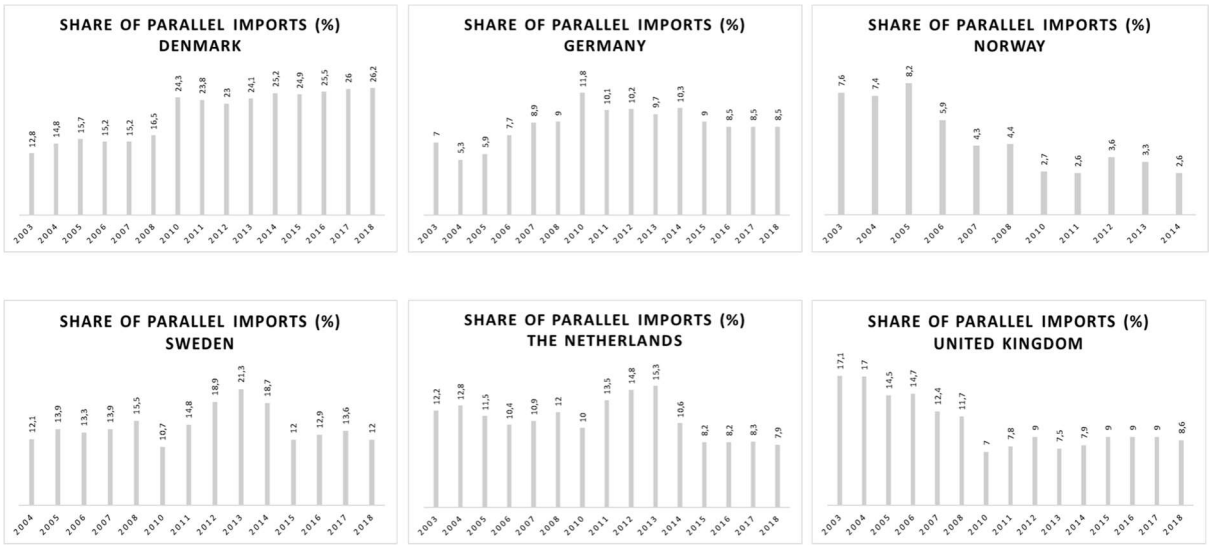
Figure 8: PT licences granted by Sweden



On the basis of this data, therefore, it is not possible to conclude that the antitrust case law on parallel trade in pharmaceuticals discussed above has had any positive impact on the development of parallel trade in these countries. At the same time, as the data show that the number of licences has not declined, this would be consistent with the view that the judgements have not had any negative effects on parallel trade. However, other factors also affect parallel imports, and notably national regulations, therefore, it is difficult to draw any strong conclusion about the impact of the judgements from this analysis.

Another source to assess the evolution of parallel trade, is the estimate the European Federation of Pharmaceutical Industries and Associations (EFPIA) has been producing over the last fifteen years of the share of parallel imports as a proportion of pharmacy sales in a number of European countries. Whilst these estimates may not be totally accurate, they represent the only publicly available estimate of the penetration of parallel imports in the destination countries.

Figure 9: Share of parallel imports



These data are consistent with the data on trade licences we discussed above, in that they show that the importance of parallel imports is not the same across all destination countries. As discussed earlier, this appears to be the result of different regulatory systems in individual Member States.

There are also significant changes over time. In three countries, namely the Netherlands, the UK and Norway, the proportion of parallel imports has decreased significantly over the time period. Note however that the change in the UK and in Norway are likely to be caused in part by currency fluctuations. The value of the British Pound against the Euro fell sharply starting in the summer 2007, and this is likely to have affected parallel imports.[57] The value of the

[57] The value of the British Pound against the Euro dropped significantly between the summer of 2007 and the beginning of 2009, and the Pound did not fully recover for some time. The Pound rose again in the second half of 2015 but fell again.

Norwegian krone against the Euro started to fall sharply in 2008, which may have contributed to slow down parallel imports.[58]

In sharp contrast, the share of parallel imports has increased substantially in Denmark in 2010 and since then these imports represent about a quarter of total pharmacy sales. In Germany and even more so in Sweden, the proportion of parallel trade has fluctuated over the years, but in both countries parallel imports account for a significant share of pharmacy sales.

Specifically, for the purpose of this working paper, the data we present do not suggest a clear effect of the *Bayer Adalat, Glaxo Greece* or *Glaxo Spain* cases, neither in facilitating parallel trade, nor in preventing it.

c. The effects of parallel trade on prices

In principle, in the absence of restrictions to trade and in unregulated markets, significant differences in the price of a product sold in different Member States are expected to spur arbitrage, and thus parallel trade.[59] Arbitrage would cause the price of the product in question to fall in the high-price countries, leading to higher consumption (the extent to which depends on the price-elasticity of demand). However, parallel imports could also lead to lower prices in the source countries. As distributors re-export the product from the low- to the high-price countries, supply is restricted in the low-price countries, leading to upward pricing pressure. Ultimately, the absence of trade restriction would lead to price convergence.

As the antitrust case law on parallel trade in pharmaceuticals does not permit the wholesale restriction of parallel trade within the EEA, we could expect parallel imports to have had some price effects, notably in the destination countries, and to contribute to price converge across the EEA countries. With this in mind, we present below the evidence we have collected on the price effects of parallel imports of pharmaceutical products.

(i) Prices in destination countries

Economic theory predicts that parallel trade should reduce prices in destination countries, because of increased competition from lower-cost alternatives. Several empirical studies that have investigated the extent to which parallel imports of particular medicines in the EEA have caused (or have been associated with) price reduction in the destination countries.

We understand that typically the price of parallel imports just undercuts that of the manufacturer's direct exports. This is confirmed by Duso et al (2014) and Mendez (2017) for oral anti-diabetic medicines in Germany and statin products in Denmark, respectively.[60] The

[58] The value of the Norwegian krone has declined sharply in 2008, and then rose back to fall again in 2012. Since then, the krone has steadily lost ground against the Euro.

[59] Naturally, it must be the case that distributors would engage in parallel trade activities if the price difference is larger than the cost of re-exporting the product from the low-price to the high-price country.

[60] T Duso, A Herr and M Suppliet, 'The welfare impact of parallel imports: a structural approach applied to the German market for oral anti-diabetics' (2014) 23 Health Economics 1036 and SJ Méndez, 'Parallel trade of pharmaceuticals: the Danish market for statins' (2017) 27 Health Economics 333.

price-reducing effect of parallel imports on the market is therefore expected to be significantly less than those of generic products, which are priced at substantially lower levels.

These two studies, which are conceptually similar, provide some insights on the effects of parallel imports, but are based on medicines for different diseases.

- Duso et al. (2014) studies the effect of parallel imports on the price of about 700 oral antidiabetics medicines that belong to six chemical groups. The data cover the period 2004-2010.
- Mendez (2017) investigates the effect of parallel imports for 213 products of the statins family (therapeutic group HMG CoA reductases inhibitors) sold in Denmark between May 2003 and March 2005.

The method employed is based on a structural economic model, which is then used to generate a counterfactual scenario in which parallel imports are banned. Prices in the counterfactual and actual scenarios are then compared.[61] Interestingly, both studies find that the market average price is lower in the counterfactual scenario without parallel imports. However, this is because part of the consumption of parallelly imported medicines would switch to generic alternatives, which are substantially cheaper than both the direct and parallel imports. Naturally, this effect is not present for on-patent medicines.[62]

That said, most economic studies we have seen, except one notable exception, find that parallel imports compete with the manufacturer's direct exports, which is to be expected. These studies concern the price of medicines sold in Sweden, Denmark and Germany. We summarise these results below.

First, Ganslandt and Maskus (2004) is one of the first economic studies that investigated this question.[63] Their study is based on the price of 164 medicines (covering 50 molecules) sold in Sweden between 1994 and 1999. This study develops a simple reduced-form regression model and find that the entry of parallel imports (which originated mostly from Italy and Spain) had a significant impact on the manufacturers' price in Sweden. The price-reducing impact ranges from 12 to 19%.

[61] These analyses rest on the econometric estimation of a nested logit demand model. Using the parameter estimates and assuming a Nash Bertrand model on the supply side with constant marginal cost, these studies simulate the equilibrium price without parallel imports.

[62] In Mendez (2017), three molecules are off-patent and three are on-patent. The results show clearly that the average price of off-patent molecule is substantially lower without parallel imports as some consumption is directed to generic. In contrast, the average price of on-patent medicines is increased in a situation without parallel imports. We note that the nested logit demand in Duso et al. (2014) and Mendez (2017) assume that within each molecule substitution patterns are proportional to market shares, irrespective of whether the product are direct exports, parallel imports or generics. A richer and more complex model may provide different results.

[63] M Ganslandt and K Maskus, 'Parallel imports and the pricing of pharmaceutical products: evidence from the European Union' (2004) 23 Journal of Health Economics 1035.

Second, Hostenkamp et al. (2012) studies the effect of parallel imports on the price paid by hospitals in Denmark.[64] The sample of data cover 347 products representing 89 substances from 2005 to 2009. That study estimates that parallel imports have a price reducing effects on statins. The estimate price effect is 11% on average, but this effect is smaller, 4%, when regional tenders instead of national ones were used.

Finally, the two studies mentioned above, Duso et al. (2014) and Mendez (2017), based on simulated equilibrium prices find that parallel imports have a reducing effect on the manufacturer's price, although the magnitude of their results differ.

- Duso et al. (2014) shows that the manufacturer price of oral antidiabetic medicines in Germany is higher by 11% on average without parallel imports. The simulated equilibrium price of generic products, however, is the same with and without parallel imports.
- Mendes (1017) finds without parallel imports the simulated manufacturer's price of statins in Denmark is about 2.5% higher. The simulated price of generic products is also 3.5% greater in the absence of parallel trade.

Another study, Kanavos and Vandoros (2010), find no significant impact on the price of medicines sold in destination countries.[65] This study is based on data from 19 medicines in six therapeutic categories, which have high volume and high price products, mostly on-patent, sold in six countries, the UK, Germany, Sweden, Denmark, The Netherlands, and Norway. The sample period runs between 1997 and 2002. This study finds no evidence that parallel trade promotes price competition in the six destination countries: no downward effects on the retail price of locally sourced medicines is recorded. Further, as penetration of parallel imports increases, their retail price converges upward, toward the price of locally sourced originator medicines.

The supply of pharmaceuticals is regulated as discussed above. In particular, in the destination countries, rules have been put in place to encourage the development of parallel imports, with the objective of reducing prices. Had pharmaceutical companies been successful at quashing parallel imports, the regulator could have sought other ways to contain medicine prices. In other words, whist parallel imports have contributed to lower manufacturer's prices in destination countries, this is not to say that regulators could not use other levers to keep prices in check. Furthermore, as we discussed below, there is a complex interplay between regulation and parallel imports, and tighter price regulation can contribute to reduce price, possibly at the expense of the distributors (wholesalers and pharmacies) and with little impact on manufacturers' profit.

These studies only concern prices in destination countries. As indicated earlier, parallel trade could also influence prices in origin countries. We are not aware, however, of any studies

[64] G Hostenkamp, C Kronborg and JN Arendt, 'Parallel imports of hospital pharmaceuticals: an empirical analysis of price effects from parallel imports and the design of procurement procedures in the Danish hospital sector' (2012) Discussion Papers on Business and Economics No. 16.

[65] P Kanavos and S Vandoros, 'Competition in prescription drug markets: is parallel trade the answer?' (2010) 31 Managerial and Decision Economics 325.

analysing such effects. We therefore turn to look at price convergence (regardless of whether prices change in the destination or in the origin countries).

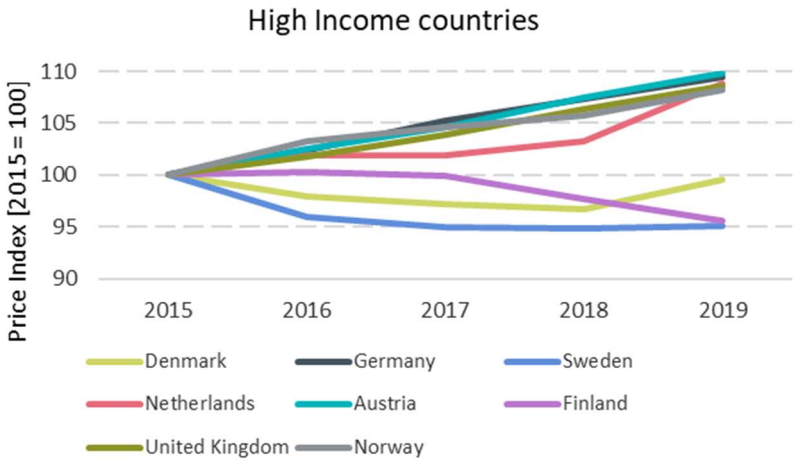
(ii) Price convergence

We have indirect evidence, using information on parallel trade licences (see section a. above), that parallel trade of authorised medicines is a significant phenomenon in the EU. In the absence of barriers to trade, parallel trade is expected to lead to price convergence between the importing and exporting countries within the Single Market. Even if not all authorised medicines are subject to parallel distribution, in principle we would expect that the most popular medicines be affected, which would influence aggregate measures of prices.

Evidence from Eurostat

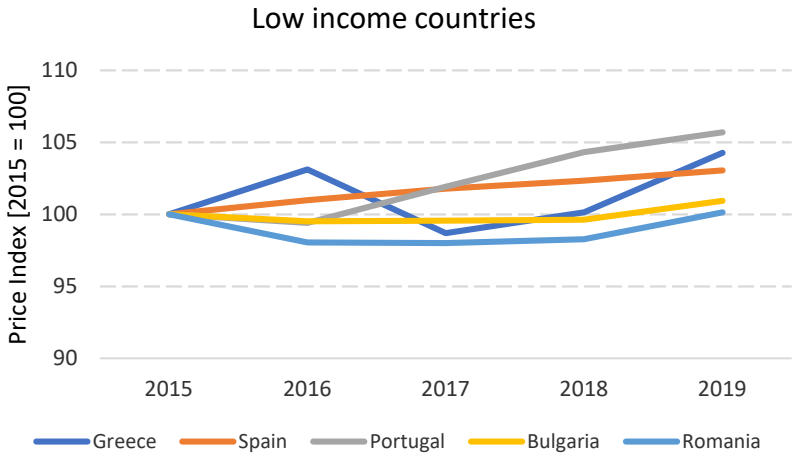
Eurostat compiles an average annual price index (HICP) on pharmaceutical products comprising medicinal preparations, medicinal drugs, patent medicines, serums and vaccines, vitamins and minerals, cod liver oil and halibut liver oil as well as oral contraceptives.[66] Whilst this is an imperfect measure in several ways, it nevertheless should provide an indication of the relative movement of the price of authorised medicines. Figure and Figure present the price index of pharmaceutical products for a select group of countries.

Figure 10



[66] As indicated by Eurostat, the prices used in the HCIP (harmonised index of consumer prices) should be the price paid by households. The HCIP is calculated according to a harmonised approach and a single set of definitions. One of the aims of the HCIP is to assess price convergence. For more information, see https://ec.europa.eu/eurostat/documents/3859598/9479325/KS-GQ-17-015-EN-N.pdf/d5e63427-c588-479f-9b19-f4b4d698f2a2.

Figure 5



In recent years, the national indices have evolved in a way that is not consistent with price convergence across exporting and importing countries. Inflation in the high-income countries, which are usually the destination countries of parallel imports, move in different ways. Inflation is significantly higher in some high-income countries (Austria, Germany, UK) than in some low-income countries, which is not consistent with convergence. In most Nordic countries, however, prices have been falling (Denmark, Sweden and Finland), a pattern that is consistent with convergence.

Evidence from the literature

Few studies have examined the extent to which prices of pharmaceutical products have been converging in the EU. We are aware of three studies whose results indicate the absence of convergence.

In a study covering 20 EEA countries using prices from IMS (MIDAS dataset) that range from 2002 to 2016, Kyle (2019) finds significant price dispersion of originator medicines in the EEA.[67] Based on a comparison of medicines widely distributed, the study shows that prices in Germany, Ireland, Sweden and Austria are about 10% higher than the EU average, and 8% and 6% for Finland and the UK respectively. In sharp contrast, prices of originator drugs in Greece, the Czech Republic, Hungary and Spain are at least 20% cheaper than the EU average, and 18% and 15% cheaper in Poland and Bulgaria respectively.

A study by Timur et al. (2011) assesses the extent of price convergence for 124 molecules that treat cardio-vascular diseases between 1994 and 2003.[68] Specifically, this study benchmarks prices in Germany against four other EU countries, controlling for quality (pack size, strength, molecule age, etc) and market characteristics. Regression results indicate price convergence relative to Germany. The convergence, however, between Germany one the one hand and

[67] M Kyle, 'The single market in pharmaceuticals' (2019) 55 Review of Industrial Organisation 111.
[68] A Timur, G Picone and J DeSimone, 'Has the European Union achieved a single pharmaceutical market?' (2011) 11 International Journal of Health Care Finance and Economics 223.

France, Italy and Spain on the other is mostly due to reduction in the "quality" of products sold in Germany.

Kyle et al. (2008) compares ex-manufacturer price dispersion in the EU with non-EU countries as control.[69] This study is based on 1023 prescription medicines in 36 categories sold in 30 countries. The data sample runs from 1993 to 2004. The study finds no evidence that price dispersion is lower in EU countries than in non-EU countries. If parallel imports would affect prices, we would expect to observer less price dispersion in the EU, where such imports are legal, whereas they are not in non-EU countries.

Both the Eurostat data and the literature therefore suggest significant price dispersion across Member States of the EU, and contain little indication that prices have been converging. This cannot be explained by the absence of parallel trade since, as we have seen above, parallel trade is clearly taking place and in some countries in significant amounts as well. The lack of price convergence must therefore be explained, *despite the existence of parallel trade*. We will discuss possible explanations for this in section d. below.

d. Factors that may explain the (limited) effects of parallel trade

There are various factors that can explain why parallel trade of pharmaceutical products in the EEA has not led to clear cut significant price effect in destination countries, and in particular has not led to price convergence.[70]

(i) The case law allows manufacturers to limit parallel imports to some extent

The case law of the European courts in cases such as *Bayer Adalat, Glaxo Greece* and *Glaxo Spain* may provide part of the explanation for the lack of (or, least, limited) effect of parallel imports on prices within the Single Market. While the CJEU has stated in these judgements that restrictions on parallel trade in pharmaceuticals may infringe EU competition law in some circumstances, it also allowed manufacturers to impose restrictions on parallel trade in other circumstances. In other words, as we explain below, manufacturers have the possibility to limit parallel imports, which might explain in particular the lack of price convergence.

The combined effect of *Bayer Adalat* and *Glaxo Greece* has mainly been to confirm the practice of pharmaceutical companies to introduce stock management systems to ensure the continued supply of authorised medicines to wholesalers and pharmacies, in accordance with the requirements of Article 81 of Directive 2001/83/EC (see also section (iii) below). In order for these systems to work, pharmaceutical companies need to adjust orders to the expected consumption requirements of the countries in question.

[69] M Kyle, J Allsbrook and K Schulman, 'Does Re-importation Reduce Price Differences for Prescription Drugs? Lessons from the European Union' (2008) 43 Health Services Research 1308.

[70] There are other reasons not discussed in this section that can explain the absence of significant effect of parallel imports on price convergence. For instance, Kyle (2011) shows that pharmaceutical companies can develop strategies to mitigate the effect of parallel trade. In particular, to limit parallel trade, firms can diversify their product offering, and specifically increase product differentiation between source and destination countries. In simple terms, pharmaceutical companies tend to supply different versions of the same medicines in source and destination countries, which reduces arbitrage opportunities.

In *Glaxo Greece* the CJEU accepted that a dominant undertaking could refuse to satisfy the orders of wholesalers which are out of the ordinary, in light of (i) the requirements of the market in question and (ii) the previous business relations with the wholesaler concerned. These two factors may not be easily applied in practice to distinguish between ordinary orders and those which are out of the ordinary. Furthermore, the domestic requirements of a specific country may not be established precisely, as these can change over time. In addition, a pharmaceutical supplier may err on the side of caution not to undersupply a market. Nevertheless, stock management systems precisely aim to ensure that supply is made in accordance with the requirements of the market concerned and are therefore based on at least one of the considerations accepted in *Glaxo Greece*. That said, because the system is not precise, parallel trade can still exist, but manufacturers may be able to limit the volumes available to be re-exported.

How this works in practice is apparent from a decision of the Hellenic Competition Commission in 2015 applying the criteria of the *Glaxo Greece* judgment. The authority ruled that a refusal by a dominant pharmaceutical supplier to supply a wholesaler is not an abuse if the quantities of the orders in question are disproportionate relative to the needs of the domestic market, and as a consequence unusual based on the previous trading relationships of the parties and the needs of the national market. To refuse to supply reasonable orders was considered abusive, however, even if the wholesalers in question, while focusing on the domestic market, also engage in some exports.[71]

The *Glaxo Spain* judgment is less explicit in this respect, but it does not exclude that restrictions of parallel trade can be justified under Article 101(3) TFEU. Moreover, the Spanish legislator has approved price-setting rules facilitating the implementation of dual pricing in Spain[72]. Pharmaceutical suppliers have used these rules to set the prices for products exported by wholesalers at a higher level, thereby significantly reducing arbitrage opportunities. However, the interpretation of these rules and its interaction with EU competition law are still the subject of disputes before the Spanish Courts.

(ii) National regulation is a major determinant of the price of pharmaceuticals and contributes to maintaining price differences between Member States

The role of parallel imports of pharmaceutical products in the Single Market may be better evaluated by accounting for the fact that the supply and pricing of medicines is highly regulated by the Member States. As discussed in section 2 above, the regulation of medicine prices varies across European countries and in fact appears to be an important factor that contributes to explain existing price differences, which in turn contribute to the persistence of parallel trade.

The prices of medicines in European countries are not typically the outcome of market forces, but mostly the result of a combination of regulation and negotiation between each country

[71] Decision 608/2015 of the Hellenic Competition Commission of 1 April 2015.
[72] See currently Article 90 of the *Ley 29/2006, de 26 de julio, de garantías y uso racional de los medicamentos y productos sanitarios*, as amended.

and pharmaceutical companies. In some countries, the regulator exerts a strict control to keep the price of new medicines low, making medicines affordable. In general, national regulators, even in countries where pricing rules are less strict, use various tools to control prices, including price freezes and price cuts.

Kyle (2011) notes that large price differences between Member States is in part due to price controls.[73] Costa-Font (2015) further argues that parallel imports in the Single Market is largely a regulation induced phenomenon.[74] In low-price countries in particular price control tends to be stricter. In this context, distributors have an incentive to resell pharmaceutical in high-price countries. As these price differences persist, so do parallel imports. After all, if prices could freely adjust, we would expect significant price convergence, arbitrage opportunities would diminish, ultimately reducing the importance of parallel imports. However, price and distribution margin differences across countries arise in large part because of the way each Member State regulates its pharmaceutical markets.

To support the thesis that parallel import is "regulatory arbitrage", Costa-Font (2015) shows that statutory distribution margins are a major factor, and not price difference, that explain the volume of parallel imports of statins (a medicine that is used to lower cholesterol) between the source countries and the Netherlands.[75] This study shows that in France, which was the major source country between 1997 and 2002), wholesaler margins were the lowest, and in the Netherlands, they were the highest. Dubois and Sæthre (2020) finds similar results using Norwegian data on all prescription medicines on patent between 2004 and 2007.[76] The study shows that the extent to which pharmacy chains in Norway steer demand toward parallel imports depends on the difference in margin between parallel and direct imports. The higher the margin earned on parallel imports, the greater the share of parallel imports.

(iii) The impact of the regulation of drug shortages

Pharmaceutical regulation does not merely cover the price of medicines but also their availability. Indeed, under Article 81 of Directive 2001/83/EC, pharma companies and distributors are required to "ensure appropriate and continued supplies of [their] medicinal product[s] to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered."[77]

Several EU Member States have tried to set up further legislative frameworks to ensure the availability of medicines and to avoid shortages. Parallel trade is often pinpointed as a cause

[73] M Kyle, 'Strategic responses to parallel trade' (2011) 11 B.E. Journal of Economic Analysis and Policy: Advances 1.
[74] J Costa-Font, 'Is medicines parallel trade "regulatory arbitrage"?' (2016) 16 International Journal of Health Economics and Management 321.
[75] Statutory distribution margins are determined by Member State regulation, which is specific to each country.
[76] P Dubois and M Sæthre, 'On the effect of parallel trade on manufacturers' and retailers' profits in the pharmaceutical sector' (2020) 88 Econometrica 2503.
[77] Article 81(2) of Directive 2001/83, introduced by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (2004) OJ L136/34.

for such shortages and some Member States have therefore introduced measures to avoid that the export of pharmaceuticals would lead to shortages.[78] One measure that is often introduced is the possibility for the relevant health authorities to issue temporary bans on the export of certain drugs, as in the Czech Republic, Estonia, France, Greece, Italy, Poland, Slovakia, Spain and Romania.[79] In addition, several EU countries have tried to stop community pharmacists from selling drugs to wholesalers (so-called reverse distribution). Finally, in many Member States a monitoring system has been set up to create early warnings for medicines which are running short. This has not stopped significant shortages from arising. In Poland, for example, all pharmacists which responded to a recent survey testified to the existence of shortages.[80]

The fear of shortages was of course amplified by the Covid-19 pandemic and the European Parliament has issued a resolution in that context which argued that "parallel exports can in some cases have the unintended consequence of creating disruptions in supply across Member States".[81] The European Commission also stated in 2019 that parallel trade may be one factor creating pharmaceuticals shortages,[82] but at the onset of the pandemic, it argued that export restrictions imposed by some Member States "contribute to the risk of shortages in other Member States, thereby putting at risk the health of people living in Europe" and were contrary to the free movement of goods.[83] Wholesalers have similarly argued that parallel trade is a balancing force that can resolve shortages in destination countries.[84] In its Communication on a *Pharmaceutical strategy for Europe* of 25 November 2020 again listed parallel trade as a possible cause of shortages but this alongside other factors such as supply quotas and issues linked to pricing and reimbursement.[85]

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[78] Affordable Medicines Europe, an association of wholesalers, lists Austria, Belgium, Bulgaria, the Czech Republic, Estonia, France, Germany, Greece, Hungary, Italy, Latvia, Norway, Poland, Portugal, Romania, Slovakia, Spain and the UK. See Affordable Medicines Europe, 'Medicine shortages: position paper' of 28 May 2020. <https://affordablemedicines.eu/wp-content/uploads/2020/06/Position-Paper-on-Medicine-Shortages.pdf>.

[79] See T. Bochenek e.a., 'Systemic measures and legislative and organizational frameworks aimed at preventing or mitigating drug shortages in 28 European and Western Asian countries' (2018) 8 Frontiers in pharmacology 942. A legislative initiative to introduce a similar system in Belgium was annulled by the Belgian constitutional court in October 2019.

[80] T. Zaprutko, 'Drug shortages as a result of parallel export in Poland – pharmacists' opinions (2020) 124 Health policy 563. Most pharmacists surveyed blamed parallel trade for the shortages.

[81] European Parliament Resolution of 17 September 2020 on the shortage of medicines – how to address an emerging problem (P9_TA(2020)0228).

[82] See Answer given in the European Parliament on 23 August 2019 by Mr Andriukaitis on behalf of the European Commission to question E-002284/2019. Other causes mentioned are manufacturing problems, industry quotas, and economic reasons such as the price of medicines.

[83] Communication from the Commission to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup 'Coordinated economic response to the COVID-19 Outbreak' COM (2020) 112 final at p. 4.

[84] See, for example, Affordable Medicines Europe, 'Trade flows of parallel imported medicines' of June 2020. <https://affordablemedicines.eu/wp-content/uploads/2020/06/Trade-Flow-Study-FINAL-big-file.pdf>.

[85] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions 'Pharmaceutical Strategy for Europe' COM (2020) 761 final at p. 17.

A major study on the effect of parallel trade on shortages has only recently been launched, again in the context of the Covid-19 pandemic, so it is hard to say whether parallel trade may cause or may alleviate medicine shortages. In any event, any national rules that prevent or disincentivise exports may limit the volumes available for parallel trade. This in turn may mute the price effects of parallel trade.

e. In the presence of parallel imports tighter price regulation, which would reduce expenditures, would mostly hurt distributors' profit

Parallel imports play an important role in the price negotiation between manufacturers and distributors/pharmacies. Specifically, parallel imports represent an alternative to the products supplied by manufacturers, and thereby they enhance distributors/pharmacies bargaining power against pharmaceutical companies. In this setting stricter price regulation would benefit manufacturers and hurt distributors.

A study by Brekke et al. (2015) builds on the fact that parallel imports affect the price negotiation between pharmaceutical companies and domestic distributors (e.g. pharmacy chains).[86] Clearly, parallel imports improve the bargaining position of distributors because, if the manufacturer seeks to raise its price, the distributor can switch to parallel imports. This change can have a profound impact on the effect of price regulation. Consider that the retail price of the pharmaceutical product is capped. A reduction in that cap would weaken the competitive constraint exerted by parallel imports. Indeed, the retail price of the original product is reduced, making parallel imports less attractive. This, in turn, weakens the bargaining power of the distributor, enabling the manufacturer to raise the price it charges the distributor. These predictions are supported empirically with Norwegian data. The study shows that for medicines with parallel imports, a lower retail price cap does not reduce the producer price and profit as much as when there are no parallel imports. In fact, in the case of medicines for which parallel imports are persistent, the reduction in the retail price cap benefit the pharmaceutical manufacturer. This finding also suggests that when price regulation is tightened, and perhaps counter-intuitively, parallel imports may help manufacturers keep their share of the industry profit, thereby maintaining innovation incentive. (See below for a more extensive discussion analysis of the effects of parallel imports on innovation.)[87]

Dubois and Sæthre (2020) builds on the notion that parallel imports is a critical factor that affects the outcome of the negotiation between manufacturers and distributors. Using the parameter estimates of a sophisticated structural model that accounts for consumer behaviour as well as the strategic interaction between the manufacturer and distribution chains, they run some simulations to show that parallel imports allow pharmacy chains to capture a substantial share of industry profit regarding the supply of Lipitor (a statin product)

[86] K Brekke, T Holmas, and O Straume, 'Price regulation and parallel imports of pharmaceuticals' (2015) 129 Journal of Public Economics 92.

[87] This study does not consider innovation and its impact on welfare. In theory, the regulator would consider not only the price of medicines but its impact on further R&D investments. Hence, it is not possible to draw any robust conclusion about the effect of parallel imports on innovation here.

in Norway between 2004 and 2007. Their results indicate that a ban on parallel imports would increase manufacturer's profit (in this case Pfizer). Interestingly, and in line with the finding of Brekke et al. (2015), their simulation also shows that a tightening of price regulation (i.e. a reduction in the retail price cap of Lipitor) would erode mostly the profit of the distribution chains and parallel importers. In other words, the savings achieved by the Norwegian government with tighter price regulation would not be a transfer from the profit of the pharmaceutical manufacturer but rather come from a significant reduction in the distributors' share of industry profit. In fact, Dubois and Sæthre suggests that the Norwegian government and Pfizer could negotiate a lower price cap, agreeing a lump sum payment that would compensate the reduction in the manufacturer's profit, and still achieve significant savings for the tax payers. Such a move would reduce arbitrage opportunities causing a fall in parallel imports.

f. The effects of parallel imports on innovation

Evaluating the impact of the case law on parallel trade in pharmaceuticals also requires an assessment of its effect on innovation.

Pharmaceutical companies have consistently argued that parallel trade undermines their incentives to make R&D investments and this issue has received much attention in the case law. The point is quite clearly made by Advocate General Jacobs in his opinion in the *Glaxo Greece* case: "Innovation is an important parameter of competition in the pharmaceuticals sector. Substantial investment is typically required in the research and development of a new pharmaceutical product. The production of a pharmaceutical product is usually characterised by high fixed costs (to research and develop the product) and comparatively low variable costs (to manufacture the product once developed)."[88] In the *Glaxo Spain* case, the Court of First Instance accepted that parallel trade "leads to a loss in efficiency for interbrand competition, in so far as it reduces GSK's capacity for innovation" whereas restrictions of parallel trade "will lead to a gain in efficiency for interbrand competition in so far as it will enable GSK's capacity for innovation to be increased."[89]

As indicated earlier, the European Commission has argued that a Single Market in pharmaceuticals may encourage R&D investments in Europe. Nevertheless, it accepts in principle that restrictions of interbrand competition (through restrictions of parallel trade) could reduce incentives for innovation, although it found in its decision in *Glaxo Spain* that the causal link between parallel trade and the loss in efficiency had not been established in practice. More precisely, and as we saw above, the Commission considered that the profits foregone through parallel trade were limited and that there was in any event no certainty that these would be invested in R&D (rather than simply being retained as additional profits).[90] The scepticism about the causal link between parallel trade and the loss in efficiency

[88] AG opinion in case C-53/03 *Syfait and Others* ECLI:EU:C:2004:673, para 89. Note that this was the opinion in the first preliminary reference in this case, which was declared inadmissible by the CJEU.
[89] Case T-168/01 *GlaxoSmithKline Services v Commission* ECLI:EU:T:2006:265, para 255.
[90] As we saw earlier, the Court of First Instance considered that the Commission should have investigated this point in more detail and this point of view was confirmed by the CJEU.

was shared by Advocate General Ruiz-Jarabo Colomer in the *Glaxo Greece* case who considered this argument "misleading, since it is aimed only at seducing public opinion, which is sensitised to the vital importance of R&D for competitiveness."[91]

To the best of our knowledge, no empirical research has been conducted concerning the impact of parallel imports on innovation in the pharmaceutical sector. Nonetheless, the economic literature provides theoretical insights, based on stylised models, about the potential effects of parallel trade on R&D investments. We will summarise the key conclusions from these models, noting that we cannot draw any robust conclusions on this important question.

We start this discussion by setting out the argument put forward by the pharmaceutical companies that parallel imports are likely to cause a reduction in innovation. This is because, in unregulated markets, parallel imports are expected to prevent pharmaceutical companies from pursuing Ramsey pricing, i.e. price discriminate, which would allow them to recoup more efficiently the fixed cost of R&D investments.[92] In other words, parallel imports erode the ability to price discriminate between markets (i.e. countries), which in turn reduces the returns that pharmaceutical companies can expect from their risky investments, notably in high price countries. Valletti and Szymanski (2006) shows that arbitrage dilutes the incentive of manufacturers to invest in higher quality products.[93] At the end of the day, consumers may benefit from parallel trade thanks to lower prices, but in the longer run, they will not have the opportunity to acquire improved products. Parallel imports, therefore, can have negative welfare effects as they reduce pharmaceutical companies' incentive to invest in developing new medicines and treatments.[94] As pharmaceutical companies operate globally, their R&D investments can be recouped by sales made everywhere around the globe. This raises the question about the extent to which parallel trade in the EEA would have decreased global revenue (and profit) of pharmaceutical companies. There is evidence that pharmaceutical innovation responds to changes in revenue. For example, Dubois et al. (2015) shows that

[91] AG opinion in joined cases C-468/06 to C-478/06 *Sot Lelos and Others* ECLI:EU:C:2008/108, para 113. Note that this was the opinion in the second preliminary reference in this case, which was declared admissible by the CJEU.

[92] For an introduction on standard economic principles on parallel trade in pharmaceuticals, see M Danzon, 'The economics of parallel trade' (1998) 13 PharmacoEconomics 293.

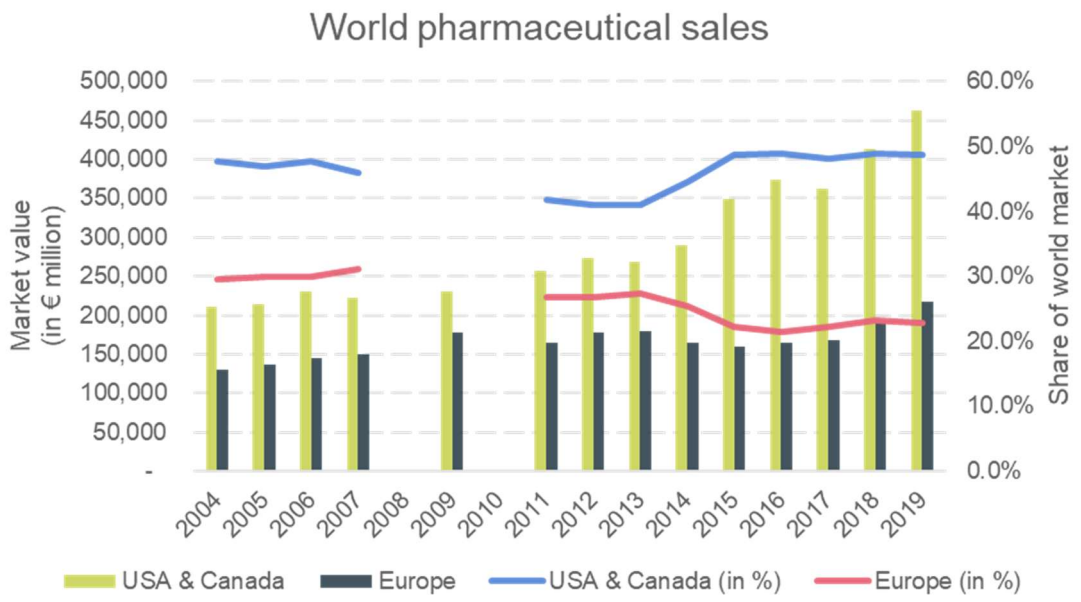
[93] T Valletti and S Szymanski, 'Parallel trade, international exhaustion and intellectual property rights: a welfare analysis' (2006) 54 The Journal of Industrial Economics 499.

[94] The basic intuition is that because parallel imports is expected to reduce the manufacturer's profit, the marginal return to investment becomes smaller, which in this case lowers the incentive to commit funds to R&D projects. That said, this need not always be the case. It depends in part on consumer preference for innovative medicines (i.e. the extent to which consumer willingness to pay for innovative medicines is increased compares to present-day medicines). It could be the case that the willingness to pay for better treatment is much higher in the low-price country, while in the high-price country, consumers would not be willing to pay more for innovation. In this setting, in theory parallel imports would impose the price in the low-price country on the high-price country, and the marginal return to investment would be higher than that in a situation without arbitrage. Indeed, the manufacturer's incremental profit depends on the higher price it can charge for the new, innovative product, which in turn depends on the willingness to pay for innovation of consumers in the low-price country. Because consumers in the low-price country value more innovation, the manufacturer could expect higher returns in a regime with parallel imports than without.

innovation, measured by the number of new chemical entities launched in 14 countries, responds to expected revenue.[95] In other words, as companies expect a drop in revenue from selling future new medicines, they would cut in their investments to develop new molecular entities.

According to the European Federation of Pharmaceutical Industries and Associations (EFPIA) the European market is an important source of the manufacturers' revenue. Figure below provides estimates of the share of total revenue generated in Europe.[96] While the North American market (USA and Canada) is clearly the world's largest, accounting for roughly 50% of global pharmaceutical sales, Europe still contributes significantly with around € 200 billion (or more than 20%) to global sales. This suggests that if parallel trade decreases profits in the EEA, it is also making a dent in global revenue and profit because the European market is relevant on a global scale. In turn, parallel trade could discourage manufacturers to engage in risky innovative investments to discover new treatments. Importantly, EFPIA also notes that for new medicines, Germany, France, Italy, Spain and the UK account for about 20% of global sales. In this context, EU policies related to parallel trade might have an impact on global R&D spending.

Figure 6



[95] Dubois et al. (2015) estimates an average elasticity of 0.23. This means that as expected revenue increases by 10%, this stimulates innovation, raising the number of new molecular entities by 2.3%. However, this study shows that the elasticity varies across ATC classes. P Dubois, O de Mouzon, F Scott-Morton and P Seabright, 'Market size and pharmaceutical innovation' (2015) 46 The RAND Journal of Economics 844.

[96] EFPIA relies on the IQVIA-MIDAS database (data relate to the audited global retail and hospital pharmaceutical market at ex-factory prices). Europe includes here Turkey and Russia, which are concerned by parallel imports.

However, because prices of medicines are regulated (or indirectly controlled), the effect of parallel imports on innovation is more complex than the basic economic logic that would have prevailed in the absence of regulation.

Grossman and Lai (2008) provides a first contribution that challenges the notion that parallel imports have a negative impact on innovation.[97] Using a stylised economic model, where the world is divided in high- and low-income countries, they show that when parallel trade is allowed to flow from the low-income to the high-income countries, the rate of innovation is improved. This is because the government in the low-income country would raise the regulatory price cap, which ultimately benefits R&D investments globally. The logic goes as follows. When parallel trade is prohibited, the pharmaceutical companies, which are located in the high-income country, will sell in the low-income country so long as the price cap is above its marginal cost of production. This allows the regulator to set relatively low prices for the benefit of consumers in that country. When parallel trade is allowed, however, the regulator in the low-income country will have to set a price that is sufficiently high to encourage the pharmaceutical companies to export in it. Otherwise, the manufacturers may walk away if the regulated price is too low, as in that case there is a significant risk that parallel imports would undercut the price of medicines in the high-income country. At the end of the day the regulator in the low-income country will set a price cap that is high enough such that the medicines are not re-exported to the high-income country.[98]

Parallel imports force the regulator in the low-income country to set high regulated prices, and this benefits the high-income country as this promotes innovation. In other words, the low-income country no longer free ride on the high-income country, which was paying for most of the R&D investments.

Bennato and Valletti (2014) challenges the finding of Grossman and Lai (2008).[99] This theoretical study shows that in some settings parallel trade may reduce innovation. This is the case when the government in the (small) low-income country cannot commit fully to a price cap (i.e. before the manufacturer decides to invest in R&D).[100] Ultimately, the regulator sets a price cap that is sufficiently high to ensure that the innovative medicine is delivered in the low-income country. However, the lack of commitment by the low-income country results in a hold-up problem, which lowers the pharmaceutical company incentive to engage in sunk R&D investments.

[97] G Grossman and E Lai, 'Parallel imports and price controls' (2008) 39 The RAND Journal of Economics 378.

[98] In this setting, the immediate consequence is that parallel imports harm consumers in the low-income country. Indeed, if parallel imports were not allowed, the regulator would be able to set a lower price and the manufacturer would sell at any price above marginal, as there is no risk that the products be re-exported in the high-income country.

[99] AR Bennato and T Valletti, 'Pharmaceutical innovation and parallel trade' (2014) 33 International Journal of Industrial Organization 83.

[100] In this set-up the government in the low-income country set the price for delivery after the manufacturer sinks its R&D expenditures but before it decides whether to deliver the new medicine in the low-income country. The government commits to a regulated price that ensures delivery, yet it does not eliminate totally the hold-up problem as this decision is made after the manufacturer decision to invest.

Reisinger, Sauri and Zenger (2019) also extends the results of Grossman and Lai (2008) by showing that the effects of parallel imports on innovation hinge on the degree of similarity between the trading countries.[101] When the demand for medicines in the high- and low-income countries are very dissimilar, parallel imports would reduce innovation. In such a case, the regulator in the low-income country would not be able to set a price cap that is sufficiently high, and thus attractive for the pharmaceutical companies to serve that country. As the manufacturer will supply only the high-income country, its returns on R&D depend on sales in that country. Instead, if parallel imports are restricted, the manufacturer will serve the low-income country, even if the regulated cap is low (but higher than the manufacturer's marginal cost). In that case, the returns on investment are higher as the innovative treatment will also be sold in the low-income country. In cases when the two countries are dissimilar, but the manufacturer serves the low-income country, parallel trade reduces innovation. This is because the price cap in the low-income country also applies in the high-income country (the price cap is exported), which dampens the incentive of the manufacturer to innovate.

On the basis of the literature review, we unfortunately cannot come to conclusive statements on the impact of parallel trade on innovation.

[101] M Reisinger, L Saurí and H Zenger, 'Parallel imports, price controls, and innovation' (2019) 66 Journal of Health Economics 163.

6. Conclusion

Health policies, including the pricing and reimbursement of pharmaceuticals, are the prerogative of Member States. In fact, the distribution and pricing of pharmaceuticals is heavily regulated in order to ensure the safety and quality of drugs, to control health care expenditures while guaranteeing access to patients and encouraging innovation.

The EU Single Market objective requires the abolition of restriction on the free movement of goods between EU Member States. In line with this policy objective, the CJEU has stated that restrictions on parallel trade in pharmaceuticals may infringe EU competition law, but it has also accepted that manufacturers impose restrictions on parallel trade in some circumstances. In particular, the CJEU has ruled that restrictions of parallel trade have as their object the restriction of competition, but that such restrictions may be justified under Article 101(3) TFEU. As regards Article 102 TFEU, it has held that a dominant undertaking abuses its position if it refuses to meet orders from wholesalers that are "ordinary" in the light of both the size of those orders in relation to the requirements of the market and the previous business relations between that undertaking and the wholesalers concerned, but not if it refuses to meet orders that are out of the ordinary.

The data available to us clearly shows that parallel imports of pharmaceutical products continue to be significant within the EEA. For instance, the data show that for a very large proportion of authorised medicines, a parallel distribution licence was granted. In addition, estimates show that parallel imports represent a small but significant proportion of medicines sold in Nordic countries, Germany, the UK and the Netherlands. However, it is not possible to conclude from this data whether parallel trade has actually increased (or decreased) as result of the CJEU's case law.

We have drawn on a review of the economic literature as well as a review of Eurostat price indices to assess the price effect of parallel imports. There is some evidence that parallel imports have contributed to reduce manufacturer's prices in destination countries: this may be explained by the fact that in these destination countries, regulation has encouraged the development of parallel imports as a way to contain expenditures. On the other hand, there is no evidence of price convergence, which is consistent with the view that parallel imports have limited price effects.

We consider that the limited price effects can be explained by at least three factors.

- The first factor is the case law. While the CJEU has ruled that restrictions on parallel trade in pharmaceuticals may infringe EU competition law in some circumstances, it also allowed manufacturers to impose restrictions on parallel trade in other circumstances.
- Second, regulation is a major determinant of prices of pharmaceuticals, and therefore price differences between Member States have persisted, whilst contributing to encourage parallel trade too.

- A third factor, finally, may be regulations aimed at preventing drug shortages both at an EU and at a national level. These regulations may reduce the volume available for parallel trade.

Importantly, the existence of parallel imports affects price negotiation between manufacturers on the one hand and distributors and pharmacies on the other. Specifically, parallel imports improve the bargaining position of the latter, enabling them to earn higher margins. Tighter price regulation in destination countries, on the other hand, would mostly erode the profit of distributors, and reduce total expenditures on medicines, without necessarily harming the returns of pharmaceutical companies.

This leads to the final critical issue, *i.e.* the extent to which parallel trade reduces the incentives of pharmaceutical companies to invest in R&D. In principle, as parallel imports erode the manufacturers' profit, they could reduce their incentive to fund risky innovative projects. However, given the interplay between price regulation, investment incentives and trade, parallel imports do not necessarily lead to reduced innovation. As we present in this paper, advances in economic theory show that the net effect will depend on the circumstances. There is unfortunately no data available to assess this issue empirically. As a result, we cannot come to conclusive statements on the impact of parallel trade on innovation.