Supplementary Material

Enhancing competition in on-patent markets

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This document presents material that supplements:
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List of acronyms/abbreviations

ATC code	Anatomical Therapeutic Chemical classification
DAA	Direct Acting Antivirals
DDD	Defined Daily Dose
EC	European Commission
EEA	European Economic Area
EMA	European Medicines Agency
EPOs	Erythropoietins
ERP	External reference pricing
EU	European Union
FDA	Food and Drug Administration
GCSFs	Granulocyte colony-stimulating factors
GORD	Gastroesophageal reflux disease
GP	General practitioner
HCV	Hepatitis C virus
HTA	Health Technology Assessment
IBM	Micromedex Red Book
ICER	Institute for Clinical and Economic Review
MEA	Managed entry agreement
NCE	New chemical entities
NHS	National Health System
NICE	National Institute for Health and Care Excellence
OECD	Organisation for Economic Co-operation and Development
PMPRB	Patented Medicine Prices Review Board
PPI	Pharma Price Information System
PPI	Proton-pump inhibitors
PPP	Purchasing Power Parity
PSD	Malaysian Pharmaceutical Service Division
RP	Reference pricing
R&D	Research and Development
SHI	Social Health Insurance
SU	Standard unit
TNF-inhibitor	Tumour necrosis factor-inhibitor
TRP	Therapeutic reference pricing

VAT	Value Added Tax
VHA	Veterans Health Administration
WHO	World Health Organization

Country abbreviations

AUS	Australia
AUT	Austria
BEL	Belgium
BGR	Bulgaria
CAN	Canada
CHE	Switzerland
CHL	Chile
COL	Colombia
CRI	Costa Rica
CYP	Cyprus[1,2]
CZE	Czech Republic
DEU	Germany
DNK	Denmark
ESP	Spain
EST	Estonia
FIN	Finland
FRA	France
GBR	United Kingdom
GRC	Greece
HUN	Hungary
IMS	Intercontinental Medical Statistics
IRL	Ireland
ISL	Iceland
ISR	Israel

[1] 1. Note by Türkiye: The information in this document with reference to “Cyprus” relates to the southern part of the Island. There is no single authority representing both Turkish and Greek Cypriot people on the Island. Türkiye recognises the Turkish Republic of Northern Cyprus (TRNC). Until a lasting and equitable solution is found within the context of the United Nations, Türkiye shall preserve its position concerning the “Cyprus issue”.

[2] Note by all the European Union Member States of the OECD and the European Union: The Republic of Cyprus is recognised by all members of the United Nations with the exception of Türkiye. The information in this document relates to the area

ITA	Italy
JPN	Japan
KOR	Korea
LUX	Luxembourg
LTU	Lithuania
LVA	Latvia
MEX	Mexico
MLT	Malta
NLD	Netherlands
NOR	Norway
NZL	New Zealand
POL	Poland
PRT	Portugal
ROU	Romania
SVK	Slovak Republic
SVN	Slovenia
SWE	Sweden
TUR	Türkiye
USA	United States

1 - Annexes

Annex A. Literature Review: Summary of studies

Table A.1. Results of the Literature review

	First author, year	Policy/Intervention studied	Geography	Outcomes	Data and Methods
1	(Arcidiacono et al., 2013[1])	○ Impact of market entry of product alternatives (both on-patent and generic medicines) on prices, use and spending in the US market of antiulcer medicines.	United States	○ Market entry of product alternatives pressured prices down, while it increased use and spending. ○ Generics and "me-too" drugs each increased consumer welfare by more than $100 million in 2010, holding insurance premiums constant. Insurance payments in 2010 fell by nearly $1 billion due to generics and rose by over $7 billion due to me-too antiulcer drugs.	○ **Data used:** product alternatives available in the US market in 1991-2010 within therapeutic classes H_2-antagonist and proton pump inhibitors to treat peptic ulcer and gastroesophageal reflux disease (GORD). ○ **Methods applied:** Econometric analysis using ordinary least squares to model demand and supply of antiulcer medicines, controlling for insurance and advertising.
2	(Bardey, Bommier and Jullien, 2010[2])	○ Impact of French's reference pricing system on the intensity and quality of innovation (in terms of product novelty), health spending, and pharmaceutical spending in France. Under this system, on-patent and generic products are reimbursed at the same maximum amount, based on the generic price.	France	○ Reference pricing affects negatively the intensity of research and it also modifies the types of innovations that are brought to the market, deterring small innovations.	○ **Data used:** data on sales of statins (Simvastatin, Pravastatin and Atorvastatin) in the French pharmaceutical market in 1989 -2010. ○ **Methods applied:** bargaining game model with three types of agents: pharmaceutical firms, consumers and a regulatory entity.
3	(Belloni, Morgan and Paris, 2016[3])	○ Analysis of the determinants of pharmaceutical expenditure across OECD countries.	OECD countries	○ Consumption levels increase, but cost-containment policies and patent expiry of several top-selling products exert downward pressure on pharmaceutical spending.	○ **Data used:** data on pharmaceutical spending of OECD countries in 1980-2016.

					○ **Methods applied:** trend analysis and review of the literature.
4	(Berdud et al., 2018[4])	○ Impact of innovation incentives (through IP rights) on the degree and nature of market competition for Direct Acting Antivirals (DAA) between 2014 and 2017.	Six European Countries (France, Germany, Italy, Portugal, Spain and the UK)	○ IP incentives for R&D (i.e. patents, data exclusivity, and supplementary protection certificates) encourage a high degree of in-class competition of DAAs close to the first entrant launch. ○ Therapeutic competition is associated with higher uptake of DAAs in the top-5 European countries.	○ **Data used:** volume sales data for products launched until June 2017, including. sofosbuvir, daclatasvir, simeprevir, ledipasvir and sofosbuvir, ombitasvir, paritaprevir and ritonavir, dasabuvir, elbasvir and grazoprevir, and sofosbuvir and velpatasvir. ○ **Methods applied:** quantitative analysis of market shares and uptake rates of DAAs. Semi-structured interviews with relevant stakeholders.
5	(Bocquet et al., 2016[5])	○ Impact of the uptake of biosimilars on the market share of their originators and other biologic alternatives of the same therapeutic class.	France, Germany, Italy, Spain, UK & Japan	○ Uptake of biosimilars seems to depend on retail/hospital distribution mixes and on medical practice and varies widely across therapeutic classes. ○ Differentials of price discounts between originators and biosimilars do not explain the uptake of biosimilars.	○ **Data used:** data on sales in 2007–2014 for two main therapeutic classes that have been 'biosimilarised' - granulocyte colony-stimulating factors (GCSFs) and erythropoietins (EPOs). ○ **Methods applied:** linear regression analysis to assess the relationship between uptakes of biosimilars and the market shares of other biologics
6	(Danzon and Chao, 2000[6])	○ Impact of price regulation on the launch prices of therapeutic alternatives.	Canada, France, Germany, Italy, Japan, UK, and United States.	○ Reduced prices for successive entrants within the same therapeutic class in less regulated markets (United States, United Kingdom, Canada, and Germany).	○ **Data used:** sales data for retail pharmacies in 1991-1992. ○ **Methods applied:** log-linear regression model to test for significant differences for product manufacturer prices between countries.
7	(Danzon and Ketcham, 2004[7])	○ Impact of reference pricing on the availability of new drugs, manufacturer prices, and out-of-pocket sur-charges to patients. Germany, the Netherlands and New Zealand cluster medicines per indication and set a maximum reimbursement amount for each cluster based on a relatively low-priced product.	Germany, the Netherlands, and New Zealand.	○ No evidence of competition among therapeutic substitutes in any of the three countries.	○ **Data used:** sales data for on- and off-patent medicines in the first half of 1998 for five major therapeutic categories: anti-ulcerants; hypoglycemics; antihyperlipidemic; antidepressants; and antihypertensives. ○ **Methods applied:** regression analysis.
8	(Danzon, Wang and Wang, 2005[8])	○ Impact of external reference pricing on firms' launching strategies.	25 major markets, including 14 EU	○ Price regulation negatively affects the timing and occurrence of market launches of medicines.	○ **Data used:** data for 85 new chemical entities (NCEs) launched between

			Member States		1994 and 1998 across the 25 major markets. ○ **Methods applied:** survival analysis (cox proportional hazard model) to simultaneously model the launch of each NCE in each country and its launch lag, relative to that NCE's first launch date within our 25 countries.
9	(Dimasi, 2000[9])	○ Impact of therapeutic competition on the launch prices of new entrants for prescription-only medicines in the US market.	United States	○ Negative association between the number of therapeutic substitutes and the price of new medicines. ○ For 20 new market entrants to existing classes, 80% were launched at a discounted price (compared to the incumbent) and 65% were launched at a discount to the average price in the class. ○ Average percentage change of - 26% relative to the price leader and -14% relative to the average price in class.	○ **Data used:** monthly claims data in 1995-1999 provided by Schneider Institute for Health Policy at Brandeis University by PCS Health Systems for the following therapeutic categories: antiarthritics, antidepressants, antihistamines, antihyperlipidemics, antihypertensives, antiulcer, and two antibiotic classes (cephalosporins and macrolides) ○ **Methods applied:** descriptive statistics.
10	(DiMasi and Paquette, 2004[10])	○ Impact of the market entry of follow-on medicines on time elapsed between market entries of successive product alternatives and competition.	United States	○ Time elapsed between entry of first-in-class and subsequent product alternatives decreased over time between 1970s and 1990s: a median of 10.2 years in the 1970s to 1.2 years for the late 1990s. ○ Approximately one-third of the follow-on new medicines received a priority rating from the USA FDA.	○ **Data used:** data included 235 follow-on drugs for 72 therapeutic classes that have been approved in the USA through 2003. ○ **Methods applied:** linear regression analysis.
11	(Ekelund and Persson, 2003[11])	○ Impact of the Swedish internal reference pricing system (introduced in 1993) on therapeutic competition between New Chemical Entities (NCEs).. There is full coverage for products that cost no more than 1.1 times the lowest-priced generic medicine in the same therapeutic class.	Sweden and the United States.	○ Internal reference pricing system discourages price competition between on-patent medicines. No significant effect of the presence of branded substitutes on either introduction prices or price dynamics.	○ **Data used:** sales data for 246 new chemical entities (NCEs) launched in Sweden in 1987-1997 provided by the Swedish Drug Market database. ○ **Methods applied:** log-linear ordinary least squares regression model to explore how the prices of patented new drugs are set relative to their existing substitutes and how these prices change over time.
12	(Ellison et al., 1997[12])	○ Quantify cross-demand price elasticities between branded and generic versions of the four anti-infective medicines.	United States	○ Prescribers are sensitive to price differentials between therapeutic substitutes.	○ **Data used:** data on the sales volume of four cephalosporins in 1985-1991. ○ **Methods applied:** regression analysis.

13	(Ellyson and Basu, 2021[13])	○ Explore the impact of market entry or potential entrants' completion of clinical trials to identify the effect of drug pipeline pressure on prices of incumbents in the markets for insulins and tumor necrosis factor (TNF)-alfa inhibitors.	United States	○ Pipeline pressure exerts cumulative and significant upward pressure on prices of incumbent drugs (around 10.5% of the growth of prices in the insulin market). ○ Insurance designs that fail to promote price competition through negotiations and value-based principles may contribute to such price increases. ○ FDA submissions by the first and second potential entrants have *no effect*, FDA submissions by the third and fourth potential entrants are associated with *increases* in the prices of incumbents.	○ **Data used:** price data (sourced by Truven Marketscan, and Medicare claims), development pipeline (clinicaltrials.gov) and molecule characteristics (FDA Redbook, Orangebook and Drugs@FDA database) on the following products: biologic insulins, biologic TNF inhibitors (etanercept, adalimumab) in 2007-2015. ○ **Methods applied:** panel data analysis.
14	(Gamba, Pertile and Vogler, 2020[14])	○ Impact of managed entry agreements (MEAs) on medicine prices in Europe.	Belgium, Greece, Italy, the Netherlands, Norway, and the United Kingdom (England).	○ The introduction of an MEA increases list prices by 5.9%.	○ **Data used:** price data on 156 medicines provided by the national competent authorities and the Austrian National Public Health Institute. ○ **Methods applied:** log-linear regression analysis.
15	(Gordon et al., 2018[15])	○ Impact of the market entry of therapeutic competitors on incumbents' prices of on-patent cancer medicines approved in the US market and covered by Medicare Part B.	United States	○ Average percent change in cost (after adjusting for inflation) for all medicines +18% (range, 216% to +59%). ○ New supplemental US FDA approvals, new off-label indications, and new competitors did not influence the annual cost change rates.	○ **Data used:** monthly costs data for 24 anticancer, injectable on-patent drugs granted FDA approval in 1996- 2012, covered by Medicare Part B. Data on average sales prices (deflated), published by the Centers for Medicare and Medicaid Services, were used to estimate discounts and rebates. ○ **Methods applied:** repeated-measures multivariable mixed-effects linear regression model.
16	(Granlund, 2021[16])	○ Impact of the market entry of patented products therapeutic alternatives on incumbents' prices in Sweden.	Sweden	○ No effect of the market entry of patented therapeutic alternatives on price of incumbents within a given therapeutic class unless more than three product alternatives are available in the market when product alternatives are predicted to reduce prices by 9%.	○ **Data used:** price data for 1586 on-patent prescription medicines sold in Sweden between October 2002 and October 2007. ○ **Methods applied:** panel data analysis using ordinary least square models
17	(Heuer, Mejer and Neuhaus, 2007[17])	○ Impact of external reference pricing on firms' launching strategies in the EU.	15 EU Member States.	○ External reference pricing is associated with longer launch timings.	○ **Data used:** data provided by IMS Drug Launches database on 132 NCE launches in the EU15 countries between 1995 and 2005. Data includes information on NCE status, trade

					name, active ingredients, marketing company, ATC and launch date. ○ **Methods applied:** probit regression analysis.
18	(Hostenkamp, 2013[18])	○ Impact of the entry of follow-on medicines on incumbents' prices and pharmaceutical spending in the Danish hospital sector.	Denmark	○ No evidence of reduced prices or lower spending in the Danish hospital market.	○ **Data used:** annual sales data from AMGROS for 17 entries of follow-on medicines entering 8 therapeutic classes in the Danish hospital sector in 2004-2009. ○ **Methods applied:** random intercepts regression analysis used to determine the estimated effects of therapeutic competition on prices of medicines.
19	(Huskamp, Epstein and Blumenthal, 2003[19])	○ Impact of a closed formulary implemented by the Veteran Health Administration (VHA) on prices, market share and health spending. The formulary includes only a limited number of medicines (usually one or two) in a class.	United States	○ The VA National Formulary was effective at shifting prescribing behaviour toward the selected medicines, achieving sizable price reductions from manufacturers, and greatly decreasing drug spending.	○ **Data used:** data provided by the Veterans Health Administration and Veterans Integrated Service Networks on prices, market share and spending for 6 therapeutic classes (ACE inhibitors, HMGs, PPIs, H2 blockers, alpha-blockers and CCBs) between 1995 and 1999. ○ **Methods applied:** log-linear regression analysis.
20	(Huskamp et al., 2005[20])	○ Impact of three-tier medicine formulary on medicine costs in the US.	United States	○ The three-tier formulary resulted in some shifting of costs from the plan to enrollees and some bargaining power gained for the payer, with plan savings from manufacturer rebates a likely result. ○ Three-tier formularies encourage consumers to choose less expensive drugs: 1) patients using first tier medicines (generics) pay the lowest out-of-pocket (OOP) costs; 2) patients of the second tier (preferred brand-name drugs) pay a higher OOP price; and, 3) patients of the third tier (non-preferred brand-name drugs) pay the highest OOP costs.	○ **Data used:** eligibility data and prescription medicine claims for three therapeutic classes (ACE inhibitors, proton-pump inhibitors (PPIs) and HMG Co-A reductase inhibitors, or statins) between 1999 and 2001. ○ **Methods applied:** multinomial logit regression models to estimate the probability of selecting a third-tier medicine.
21	(Kaiser, Mendez and Rønde, 2010[21])	○ Impact of a policy change in Denmark in 2005: therapeutic reference pricing replaced external reference pricing. The new policy takes the minimum domestic prices (based on the EU average) to	Denmark	○ Medicine prices decreased significantly (more than 26%) after the policy change. ○ Patient co-payments decreased by 3% while government expenditure decreased by 5.6% and maunfacturers' revenues by 5%.	○ **Data used:** Data provided by the Danish Medicines Agency on prices and sales of statins sold in the Danish market between 2003 and 2006. ○ **Methods applied:** panel data analysis using ordinary least square model.

		assign a reference price to a reference group of medicines which are considered theraeutci alternatives.			
22	(Kanavos and Vandoros, 2011[22])	○ Determinants of pricing of on-patent medicines across various regulatory regimes.	15 OECD countries	○ Product age (i.e. time in the market) has a significant effect on prices in all settings. Newer products or classes of medicines are on average higher priced than older (classes of) medicines ○ Price convergence across countries for newer prescription medicines compared with older medicines. ○ Profit margins along the supply chain and taxes are important determinants of retail prices in several countries.	○ **Data used:** sales data provided by national official sources and IMS on 50 leading originator prescription-only medicines in 2004 and 2007. ○ **Methods applied:** panel data analysis using log-linear regression analysis.
23	(Kanavos et al., 2012[23])	○ Evaluation of tendering and rebate contracts for (mainly off-patent) medicines in Germany and the Netherlands.	Germany and the Netherlands	○ Tenders reduced prices close to marginal cost. ○ One-company-wins-all used as the tendering award procedure in most cases for both the Netherlands and Germany. ○ In Germany, up to three companies that are allowed to supply the market.	○ **Data used:** data on prices of medicines that were procured under tendering and rebate contracts in Germany and the Netherlands between 2008 and 2011. ○ **Methods applied:** literature review, semi-structured interviews with stakeholders and descriptive statistics.
24	(Kanavos, Font and McGuire, 2007[24])	○ Impact of the entry of therapeutic alternatives on launch prices of entrants and incumbents' prices in the market for statins in four EU countries.	The United Kingdom, Germany, France, and the Netherlands	○ No evidence of price reduction. Competitors follow a price differentiation strategy in all countries. ○ Entry of additional statins did not affect prices of the first two statins. ○ Prices of followers are close to or below the incumbents.	○ **Data used:** Data on prices for statins entering the market between 1991 and 2002 in the United Kingdom, Germany, France, and the Netherlands. ○ **Methods applied:** panel data analysis using two-stage least squares model.
25	(Kanavos et al., 2013[25])	○ Determinants of pharmaceutical spending and the impact of value-based pricing on pharmaceutical spending.	Australia, Canada, France, Germany, Switzerland, the United Kingdom, and the United States	○ Higher US per capita pharmaceutical spending is partly due to faster uptake of new and more expensive prescription medicines compared to other countries, which may be attributable to how value is assessed. ○ Most countries assess the value of new medicines using clinical comparative effectiveness and cost-effectiveness analyses.	○ **Data used:** Data provided by the IMS Health MIDAS database on prices, volume, and sales for medicines under patent protection in Australia, Canada, France, Germany, Switzerland, the United Kingdom, and the United States in 2005, 2007, and 2010. ○ **Methods applied:** Descriptive statistics.
26	(Kyle, 2007[26])	○ Impact of price controls on firms' launching strategies across OECD countries.	OECD countries	○ Countries with price controls associated with lower probability of launch of new products; .	○ **Data used:** Data on NCEs developed between 1980 and 2000 provided by Pharmaprojects Database, OECD Health Database, and Urch Publishing.

		○ Price controls refer to price caps imposed on either the ex-manufacturer price or the maximum reimbursement price.		○ Price controls have differential effects on foreign and domestic firms, negatively affecting those firms that decide to launch internationally.	Data includes the medicine's chemical and brand names, originators' name and nationality. ○ **Methods applied:** ordinary least square regression analysis.
27	(Leopold et al., 2012[27])	○ Impact of external reference pricing on on-patent medicine prices in 14 European countries. External reference pricing refers to the practice of using the price(s) of a medicine in one or several countries to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country.	Austria, Belgium, Denmark, Germany, Greece, Finland, France, Italy, the Netherlands, Norway, Portugal, Spain, Sweden, and the Slovak Republic	○ ERP associated with reduced prices of on-patent medicines. ○ However, there is large variation subsides in price levels among countries using ERP.	○ **Data used:** price data provided by the Pharmaceutical Price Information (PPI) Service of the Austrian Health Institute on 14 on-patent medicines sold between 2007 and 2008. ○ **Methods applied:** linear regression analysis.
28	(Lexchin, 2006[28])	○ Impact of competition on the launch prices of follow-on medicines in the Canadian pharmaceutical market.	Canada	○ Evidence of some degree of price competition when there are at least four competitors in a therapeutic class, though this result only applies for seven of 33 reviewed medicines.	○ **Data used:** price data provided by Patented Medicine Prices Review Board (PMPRB) reports on all new active substances evaluated by PMPRB between 1994 and 2003. ○ **Methods applied:** Descriptive statistics.
29	(Lichtenberg and Philipson, 2002[29])	○ Impact of competition between on-patent medicines on originators returns of R&D based firms.	United States	○ Competition between patented medicines reduces originators' returns similarly to off-patent competition caused by patent expiration.	○ **Data used:** Medicaid sales data on all approved prescription-only medicines between 1982 and 2001. Data provided by the Medicaid State Drug Utilization Data files, FDA Orange Book and National Drug Code Directory. ○ **Methods applied:** panel data analysis using log-linear regression models.
30	(Lising et al., 2017[30])	○ Impact of health technology assessment (HTA) on formulary management mechanisms in the US market.	United States	○ Likely an important impact of the use of the Institute for Clinical and Economic Review (ICER) value assessments on formulary decision-making processes in the US market as the current use of the assessments by decision-makers is high.	○ **Data used:** surveys on US payers' use of ICER reports. ○ **Methods applied:** survey analysis.
31	(Liu et al., 2021[31])	○ Impact of the market entry of therapeutic alternatives on incumbents' prices of medicines	United States	○ No evidence of price competition among therapeutic alternatives.	○ **Data used:** price data provided by the Micromedex Red Book (IBM) on 4 DOACs, 4 SGLT2 inhibitors, 4 DPP4 inhibitors, 7 GLP-1 receptor agonists,

		treating chronic conditions in the US market.			and 2 P2Y12 inhibitors between 2015 and 2020. ○ **Methods applied:** cross-sectional analysis.
32	(Lu and Comanor, 1998[32])	○ Impact of on-patent competition on launch prices.	United States	○ Launch prices of medicines with added therapeutic benefits can be two or three times those of existing product alternatives. ○ Number of patented substitutes negatively associated with launch prices.	○ **Data used:** data on 144 new on-patent medicines granted FDA authorization between 1978 and 1987. Data includes information on prices, indications, FDA approval date, therapeutic rating, product's mode of administration. ○ **Methods applied:** log-linear ordinary least square regression analysis.
33	(Maini, 2020[33])	○ Potential consequences if the US adopts external reference pricing on access to on-patent medicines in the European Economic Area (EEA).	EEA member states	○ The implementation of ERP in the US would lead to launch delay in other markets with negative spillover effects over the effectiveness of ERP (namely reducing savings and decreasing access to medicines) in those countries referenced by the US.	○ **Data used:** data provided by IQVIA MIDAS database and EMA's website on sales and approval and launch dates of 481 on-patent medicines sold between 1995 and 2012. Data provided by Eurostat, ECB, Global Burden of Disease on GDP, population, exchange rates, and the incidence of diseases. ○ **Methods applied:** agent model of entry across multiple markets.
34	(Morton and Boller, 2017[34])	○ Impact of the use of formulary management mechanisms by health insurers on therapeutic price competition.	United States	○ Formularies associated with price competition between on-patent medicines.	○ **Data used:** literature review of US studies until 2015 ○ **Methods applied:** systematic literature review and descriptive statistics.
35	(Mueller and Frenzel, 2013[35])	○ Impact of new entrants on the launch prices of follow-on medicines in the German market.	Germany	○ Follow-on medicines induce price competition. ○ Largely unchanged prices after 4 years may be interpreted as quality competition and can be attributed to prices in Germany being anchor points for external reference pricing	○ **Data used:** sales data from the IMS Health database on new molecules launched in the German market between 1993 and 2008. ○ **Methods applied:** log-linear ordinary least square regression analysis.
36	(Pavcnik, 2002[36])	○ Impact of changes in reimbursement rules (from a flat prescription fee to a maximum reimbursement amount) on medicine prices in 1989 in Germany.	Germany	○ This change in reimbursement policy exposes the patient to the price of a prescribed product and thus potential higher out-of-pocket expenses. Prices decreased after this change as well as the potential patient out-of-pocket expenses	○ **Data used:** sales data provided by from the IMS Health database on oral antidiabetics and antiulcerants (H2 antagonists) starting in 1989. ○ **Methods applied:** panel data analysis using regression model.

37	(Petrou, 2016[37])	○ Impact of tendering on medicine prices (both inpatient and outpatient) in Cyprus.	Cyprus	○ Tendering associated with price reductions, that are greater to the price reductions realized under external price referencing.	○ **Data used:** sales data provided by the Ministry of Health on 36 patented medicines procured by tendering and that were continuously included in the national formulary between 2006 to 2012. ○ **Methods applied:** Regression analysis using generalized linear models.
38	(Petrou and Talias, 2014[38])	○ Impact of tendering on prices. Cyprus uses tendering for inpatient and outpatient medicines.	Cyprus	○ For on-patent medicines, prices decreased on average 26% leading to 33% in expenditure savings.	○ **Data used:** sales data provided by the Ministry of Health on 178 products selected based on budget impact, volume, and clinical importance. These products represented EUR 50M in annual expenditure. ○ **Methods applied:** descriptive statistics and Wilcoxon Signed ranks testing.
39	(Puig-Junoy and López-Valcárcel, 2014[39])	○ Determinants of launch prices of new medicines sold in the Spanish pharmaceutical market.	Spain	○ Relative launch prices are negatively correlated with the number of competitors on the market and positively correlated with a product's being approved through the EMA centralised procedure.	○ **Data used:** price data provided by the Ministry of Health on 114 new medicines covered by the NHS and sold in Spain between 1997 and 2005. ○ **Methods applied:** log-linear ordinary least square regression analysis.
40	(Roediger et al., 2019[40])	○ Impact of therapeutic competition on prices levels, market share, and product's lifecycle in the HCV market.	Austria, Belgium, France, Germany, Italy, Spain, and United Kingdom	○ Therapeutic competition leads to decreases in prices and market share but also often shortens the product's lifecycle to only a fraction of the patent period.	○ **Data used:** monthly sales data on the HCV market between 2011 and 2017, gathered from IQVIA and GERS Data. ○ **Methods applied:** descriptive statistics.
41	(Rudholm, 2003[41])	○ Analysis of product substitutability between patented medicines (prescription-only) in the Swedish market.	Sweden	○ Product substitutability exists among patented medicines.	○ **Data used:** Data on the prescription drug market for beta-receptor blocking agents, the 'over the counter' market for purgatives and the hospital market for two gastric ulcers medicines between 1977 and 1996. Data was provided by Swedish Medical Products Agency and includes information on prices, volumes sold in each quarter, for the package size with the largest registered sales volume.

					○ **Methods applied:** ordinary least square and three-stage least squares regression analysis.
42	(Sarpatwari et al., 2019[42])	○ Impact of policies such as fast approval mechanisms on price competition.	United States	○ Policies, such as accelerating approval of non-first-in-class drugs, will likely not result in lower medicine list prices.	○ **Data used:** Literature review of studies on on-patent competition in the US market published in English between January 1990 and April 2019. ○ **Methods applied:** systematic literature review.
43	(Stargardt, 2011[43])	○ The impact of reference pricing and temporary price freezes on medicine prices in the German market. ○ Germany uses three different types of reference pricing: (1) generic reference pricing, (2) therapeutic reference pricing inc. single-sourced medicines, and (3) reference pricing for multi-source medicines. Germany also imposes price freezes, i.e. manufacturers must give rebates to the SHI funds corresponding to any price increase since the beginning of the price freeze.	Germany	○ Reference pricing and temporary price freeze exert downward pressure on medicine prices in Germany. There is no evidence of the impact of these policies on volumes.	○ **Data used:** Techniker Krankenkasse database on prices, volumes, and product characteristics of 1,966 different substances that belonged to 661 different medicine classes between 2004 and 2006. ○ **Methods applied:** multilevel regression models.
44	(Straume, 2023[44])	○ Impact of therapeutic reference pricing on price competition.	N/A	○ Therapeutic reference pricing does not shift manufacturers' incentives away from investing in 'me-too' innovations. Therapeutic reference pricing reduces firms' incentives to differentiate their products leading to the market entry of less differentiated products from the incumbents.	○ **Data used**: N/A ○ **Methods applied:** theoretical model using Hoteling's framework.
45	(Visante, 2017[45])	○ Impact of medicine formularies on medicine prices. In the US, pharmacy benefit managers negotiate rebates for medicines included in formularies, which contain a list of medicines covered by a health plan.	United States	○ No correlation between price increases and rebates for top 200 patented medicines. ○ Manufacturers increase prices even when rebates are low in major therapeutic classes. ○ Rebates are unrelated to the launch prices of new medicines.	○ **Data used:** Data provided by SSR Health on list and net prices and gross sales between 2007-2016 for the top 200 self-administered, patent-protected medicines. ○ **Methods applied:** Descriptive statistics.

47	(Vokinger et al., 2022[46])	○ Impact of the entry of therapeutic alternatives on prices for cancer medicines.	Germany, Switzerland, and the United States	○ No evidence of therapeutic competition on cancer medicines in the US. ○ Price negotiations, as applied in Germany or Switzerland, could help address US high prices on cancer medicines.	○ **Data used:** Price data provided by the FDA database and European Medicines Agency's database on cancer drugs approved for the treatment of solid cancers in the US and Europe between 2009 and 2020. ○ **Methods applied:** Descriptive statistics and correlation analysis.
48	(Wiggins and Maness, 2004[47])	○ Impact of the market entry of therapeutic alternatives on prices in the US markets for anti-infectives.	United States	○ Entry of therapeutic alternatives is associated with price reductions.	○ **Data used:** pharmacy transaction data from the IMS health database on anti-infective products between 1984-1990. ○ **Methods applied:** least squares regression analysis.
49	(Windmeijer et al., 2005[48])	○ Impact of pharmaceutical promotion on prescribing behaviour and price effects of external reference pricing. ○ The Netherlands adopted the Pharmaceutical Prices Act in 1996, which established an external reference pricing (ERP) to reference price medicines using a weighted average of the prices of simialr medicines in surrounding countries.	The Netherlands	○ ERP associated with price reductions in markets for anti-hypertensives and anti-depressants. ○ Price sensitivity of prescribers is low and likely to be affected by marketing and promotion strategies of manufacturers.	○ **Data used:** data by the IMS Health database on monthly medicine prescription and data on monthly outlays on medicine promotion for 11 therapeutic markets between 1994 and 1999. Eleven therapeutic markets are: hypertension, ulcers, cholesterol, pregnancy, depression, rheumatism, migraine, anxiety, asthma, sleeping disorders and allergies with a special focus on the markets for anti-hypertensives and anti-depressants. ○ **Methods applied:** Descriptive statistics.

Source: Authors

Annex B. Data and methodology

IQVIA MIDAS™ database

The data for this analysis is provided by IQVIA from the MIDAS™ database on quarterly sales, prices, and volumes sold of first-in-class and subsequent entrants for each therapeutic class and country in the period between 1997q4 and 2021q4. Box B.1. outlines IQVIA's data collection process according to the distribution channels in which the sales takes place.

Box B.1. Process of data collection by IQVIA

Sales data is collected according to the distribution channel of a product pack in the country, as shown in Figure B.1. Since most countries have a separate retail and hospital panel, to reflect the different channels of distribution within a country, there are four types of panels used for data collection:

Figure B.1. Sales data collection

Source: Authors based on information provided from IQVIA

Table A B.1. Retail sales data collection

Retail sell in - supply	Retail sell in - demand
The most widely available MIDAS panel type available in more than 70 countries Measures sales in numbers of packs of products from wholesalers to retail pharmacies Provides valuable clues to changes in competitor supply	Is a newer source of data for IQVIA Measures the level of dispensing in packs of products from retail pharmacies to consumers The source is pharmacy sales receipts which provide an accurate view of actual in-country sales

Most established data collection methods with the lowest level of data protection required	

Source: Authors with input from IQVIA.

Table A B.2. Hospital sales data collection

Hospital sell in - supply	Hospital sell in - demand
Available in over 30 countries worldwide The data can be obtained from wholesalers or hospitals, but always represents the supply to hospital pharmacy regardless of source Provides valuable clues to changes in competitor supply	Hospital consumption data measures the dispensing of doses to patients within hospital wards Hospital consumption panels are not measuring how many packs of a product were purchased from wholesalers, but instead the usage of tablets, injections, etc in treating patients in the hospital.

Source: Authors with input from IQVIA.

IQVIA MIDAS™ database contains several variables providing more detailed information to characterise sales data, products and companies as described in Table A B.3. For a given product, IQVIA provides sales data from different sectors, manufacturers, and presentations (pack size and/or volume). IQVIA provides data on products prices standardised (in Standard Units (SUs) as detailed in Box B.2) to comparable quantities and doses across different product pack sizes and pack volumes within each class. For this analysis, standardised quarterly average prices and volumes were then aggregated by therapeutic class and country. For each therapeutic class, the analysis spanned the period from the date of market entry[3] of the first-in-class product to the date of entry of the first generic, biosimilar, or fixed dose combination of any of the products in the class. This was done to exclude the effect of generic, biosimilar or fixed-dose combination market entry on prices[4]. Prices were adjusted both for inflation and currency fluctuation.

Table A B.3. List of variables provided by IQVIA from the MIDAS™ database

	Variables	Information
Sales data	Quarterly sales value in Local currency sales (LC USD)	Converted to US dollars at constant exchange rates.
	Quarterly ex-manufacturer price	Wholesaler purchase price and the manufacturers' selling price.
	Quarterly volume	The number of standard 'dose' units sold in Standard Units (SUs) (see Box A B.1. for more detailed information). This is determined by taking the number of counting units sold divided by the standard unit factor which is the smallest common dose of a product form as defined by IQVIA.

[3] Market entry is defined as the date of first sale of a product in a country. In Germany, Norway and the United Kingdom, for example, where coverage by the main national coverage scheme is not conditional on a centralised process to determine prices, the first sale of a given product may be expected to occur shortly after MA, whereas in France, Italy and Spain, the first sale may be likely to occur only after completion of the pricing and coverage process and a positive coverage decision.

[4] Three molecules face generic competition during the time of study: dasatinib, imatinib and insulin glargine. Generic competitors do not enter the market at the same time in all countries as shown in Table A B.4.

Product characteristics	International product	Groups the products which are sold under different brand names with the same active ingredient and corporation entries.
	International pack size	International pack size is a standardization of the description of pack size (i.e., number of items within a pack) used for non-liquid forms. For example: the number of items in one pack such as a box of 6 injection vials is equivalent to 6 units; a pack of 3 foils, each of 21 tablets, is equivalent to 63 units;
	International pack volume	It is the volume of the pack; used for liquid forms.
	Sector: Hospital vs Retail	Whether the medicine product is sold for the hospital or retail sector.
	Molecule list	Whether the medicine product composition is a molecule or a combination of molecules.
	Estimated protection expiry date	It is the estimated month and year of the protection expiry date of a product.
	Generic product classification	Market Segmentation classification according to the IQVIA definition of a generic/non-generic product.
	Generic biosimilar availability	Yes/No depending on whether a generic or a biosimilar is available for the given molecule and country.
	Estimated Protection Expiry date	Estimated month and year of the protection expiry date of a product.
	Chemical Salt	Salt of compounds in the product.
	Time period of first generic launch	Quarter in which generics were launched for the given country and molecule.
Company level information	Corporation	The corporation is the owning company (international).
	Manufacturer	The manufacturer is a local marketing company.

Source: IQVIA from the MIDAS™ database.

Box B.2. Definition of Standard Unites (Sus) by IQVIA

Standard units (Sus) are used when the packs or products being compared are different in form.

$$SU = Units \times CU\ factor / SU\ factor$$

Where:

- Units are the number of packs that have been sold for a particular product.
- CU factor is the number of counting units in one pack
- SU factor is the number of counting units in one dose for this pack.

For example:

- 12,500 packs, each containing 100 aspirin tablets. The dosage is one tablet.

  $SU = 12{,}500 \times \frac{100}{1} = 1{,}250{,}000$, where:

- 12,500 is the number of packs that have been sold
- 100 is the number of tablets in one pack (the counting unit factor)
- 1 is the standard unit factor since there is one counting unit (tablet) in a dose.

- 16,000 packs, each containing 100ml of penicillin suspension. The dosage is 5 ml.

  $SU = 16{,}000 \times \frac{100}{5} = 320{,}000$, where:

- 16,000 is the number of packs that have been sold
- 100ml is the number of millilitres in one pack (the counting unit factor)
- 5 is the standard unit factor since there are 5 counting units (mls) in a dose of 5 ml

Source: Authors with input from IQVIA

For each product class, the period analysed spans from the time of the market entry of the first-in-class product to the time of entry of the first generic or biosimilar version of any of the products in that class[5]. IQVIA MIDAS™ database provides the date of generic (biosimilar) entry for a given therapeutic class in each country. Both the descriptive and the econometric analysis consider only the period before generic (biosimilar) entry. For example, for France, data on the TKI class would stop at Q4 2016. This is done with the intention of excluding the effect of generic or biosimilar entry on prices of originator products in each class. Therefore, graphical visualisations will show a time series starting at the quarter first sales of a product are reported[6]. Three molecules face generic competition during the time of study: *dasatinib*, *imatinib* and *insulin glargine*. Generic competitors do not enter the market at the same time in all countries. See Table A B.4 for detailed information on date of generic entry at country level.

Definition of market entry

Market entry is defined as the first sale of a product entering the market in a country. The first sale of a competing product is the event expected to initiate competitive pressure in a class and can therefore be hypothesised to influence prices. However, earlier events could also affect prices, if incumbents adjust their pricing strategies in anticipation of the arrival of a competitor.[7]

Table A B.4. Date of generic entry

Country/product	dasatinib	imatinib	insulin glargine
France	Q3 2019	Q4 2016	Q1 2016
Germany	Q1 2019	Q4 2016	Q3 2015
Italy	Q3 2019	Q1 2017	Q1 2016
Spain	Q2 2021	Q4 2016	Q4 2015
Sweden	Q2 2019	Q4 2016	Q3 2015
Norway	-	Q3 2016	Q4 2015
UK	Q1 2020	Q4 2016	Q2 2015

Source: Data retrieved from IQVIA MIDAS™ database.

Furthermore, for estimation of Model 1 and 2 (further described in the Econometric Analysis section), one price is calculated for the therapeutic class for each period. This price is once

[5] In the case of the GLP-1 receptor analogues and insulin analogues, until the market entry of the first combination product, whichever occurred earlier.

[6] After consulting with IQVIA, quarters in which reported sales were 0, were interpreted as missing data

7 For example, the following earlier events were analysed in prior studies: publication/announcement of successful Phase 3 clinical trial results (Ellyson and Basu, 2021[13]); marketing authorisation in the jurisdiction (Lu and Comanor, 1998[32]; Mueller and Frenzel, 2013[35]); and a positive pricing and coverage decision in the jurisdiction (Ekelund and Persson, 2003[11]).

again a weighted average, but this time of the prices of therapeutic alternatives available in the given class.

Econometric analysis

Panel data regression analyses explored whether entry of successive products statistically significantly explain changes in prices and volumes in each of the countries in scope, accounting for country specific and market specific characteristics during the period of analysis. Coefficients were estimated pooling across countries and therapeutic classes. When considering average prices at the level of a therapeutic class, a potential effect of market entry can be driven by new entrants being discounted to gain market share and by price reductions by incumbents in response to new entrants. These effects could be tested separately by excluding prices of new entrants from the analysis or including them. On this basis, the following models were estimated (Table A B.5):

- Model 1 testing the hypothesis that new entrants into the class decrease prices of first-in-class;
- Model 2 testing the hypothesis that new entrants decrease average prices in the class, through decreases in prices of first-in-class or lower prices of new entrants; and,
- Model 3 testing the hypothesis that new entrants into the class increase the market size in the class.

Table A B.5. Econometric models and hypotheses to be tested

Model	Hypothesis	Dependent variable	Explanatory variables
1	New entrants into the class decrease prices of incumbents in the class	Normalised product price in the therapeutic class, *excluding* the latest entrant	Variables of interest: indicator variables of market entry for each successive entrant Control variables: Year fixed effects (and time trend that is country specific) Time-invariant therapeutic class and country fixed effects
2	New entrants decrease average prices in the class, through decreases in prices of incumbents or lower prices of new entrants	Normalised product price in the therapeutic class, *including* prices of incumbents and entrants in all time periods	Variables of interest: indicator variables of market entry for each successive entrant Control variables: Year fixed effects (and a time trend that is country specific) Time-invariant therapeutic class and country fixed effects
3	New entrants into the class increase the market size in the class	Growth in volume and sales per product	Variable of interest: logarithm of the number of therapeutic alternatives in the same class Control variables: Year fixed effects (and time trend that is country specific) Product fixed effects

Note: The model specified to estimate effects on prices of entrants in Models 1 and 2 is similar to that proposed by Lu and Comanor (1998[32]) and replicated by (Ekelund and Persson, 2003[11]) and Mueller and Frenzel (2013[35]). Model 3 uses specifications as per (Lichtenberg and Philipson, 2002[29]).
Source: Authors.

***Model 1*: New entrants into the class decrease prices of incumbents in the class**

2. This is tested pooling data for all countries in the sample and estimating the following specification:

$$p_{i,t,c}^{ex} = \alpha + \beta_k \sum_{k=1}^{k-1} D_{k,i,t} + \delta_t + \lambda_k + \psi_c + u_{i,t,c} \text{ (Model 1)}$$

Where $p_{i,t,c}$ is the weighted average price in therapeutic class *i* in country *c*, excluding the latest market entrant. α is a constant; $D_{k,i,t,c}$ are defined as market entry dummies, which takes the value of 1 if entrant *k* in therapeutic class *i* has entered the market at time *t* for country *c*, and 0 otherwise. $\delta_t$represents a time trend, where multiple alternatives were estimated (see section on robustness checks).

Finally, λ_k and ψ_c are fixed effects for therapeutic class and country, respectively.

***Model 2*: New entrants decrease average prices in the class, through decreases in prices of incumbents or lower prices of new entrants**

This is tested pooling data for all countries in the sample and estimating the following specification:

$$p_{i,t,c}^{inc} = \alpha + \beta_k \sum_{k=1}^{k-1} D_{k,i,t} + \delta_t + \lambda_k + \psi_c + u_{i,t,c} \text{ (Model 2)}$$

Where $p_{i,t,c}$ is the weighted average price in therapeutic class *i* in country *c*, including the latest market entrant. α is a constant; $D_{k,i,t,c}$ are defined as market entry dummies, which takes the value of 1 if entrant *k* in therapeutic class *i* has entered the market at time *t* for country *c*, and 0 otherwise. δ_t represents a time trend, where multiple alternatives were estimated (see section on robustness checks).

Finally, λ_k and ψ_c are fixed effects for therapeutic class and country, respectively.

***Model 3*: New entrants into the class increase the market size in the class**

This is tested using the same specification as Lichtenberg and Phillipson (2002)

$$\Delta \ln Q_{m,t} = \alpha \ln N_{m,t} + \phi_m + \delta_t + u_{m,t} \text{ (Model 3)}$$

Where $Q_{m,t}$ is the quantity sold of product m in period t, i.e. the quarterly volume sales in the number of products sold. $N_{m,t}$ is the number of therapeutic alternatives in the same class as product m in period t, ϕ_m are product fixed effects and δ_t is a time trend (see section on robustness checks) [8].

Robustness checks

To ensure the robustness of the models estimated for the quantitative analyses, alternative specifications of Models 1-3 were also considered. These included using different specifications, including:

- Different specifications to model time trends including:
  - i) yearly dummies
  - ii) linear and quadratic time trend, t and t^2, respectively
  - iii) yearly dummies with a country-specific linear time trend.

[8] This log-linear specification is appropriate if, as we believe, there are diminishing marginal effects of entry on incumbent sales, for example, if the first entrant's sales are reduced more by entry of a second firm than they are by entry of a third firm (Lichtenberg and Philipson, 2002[29])

- Sub-sample estimation based on disaggregation of the retail and hospital sector: For this, the original sample was split according to the distribution channel. The relevant variables were then constructed for each sample and regressions were then estimated again.

Summary statistics at the country level

France

Table A B.6. France: summary statistics, 1997q4 and 2021q4

Therapeutic Class	First-in-class product					Follow-on products				
	Mean	Median	S. Dev.	Min	Max	Mean	Median	S. Dev.	Min	Max
direct oral anticoagulant										
Price (USD per SU, quarterly)	1.50	1.16	0.64	0.97	2.51	2.24	2.00	1.34	1.03	5.89
Volume (Thousand SU, quarterly)	76000.00	49070.00	75270.00	1.28	234300.00	75370.00	53060.00	70350.00	13.71	217100.00
Market share (Quarterly)	0.43	0.34	0.30	0.074	1	0.65	0.77	0.27	0.071	0.93
Class averages										
Price (USD per SU, quarterly)	1.45	1.21	0.50	0.93	2.51	2.18	2.13	1.09	0.91	5.89
Volume (Thousand SU, quarterly)	8246.00	3255.00	9067.00	0.02	35170.00	61630.00	27030.00	81890.00	0.08	393400.00
Market share (Quarterly)	0.42	0.34	0.30	0.04	1.00	0.68	0.77	0.26	0.01	0.97
insulin analogue										
Price (USD per SU)	12.00	12.14	0.53	10.17	14.49	11.84	12.03	0.31	11.45	12.67
Volume (Thousand SUs)	3812.00	3997.00	1814.00	7.10	6539.00	893.34	953.19	393.87	0.70	1402.00
Market share	0.84	0.79	0.09	0.77	1	0.19	0.22	0.051	0.00039	0.23
Class averages										
Price (USD per SU, quarterly)	11.44	11.64	2.51	7.88	40.02	11.81	11.50	3.06	8.00	27.74
Volume (Thousand SU, quarterly)	1791.00	1797.00	1419.00	0.23	5137.00	761.43	717.66	640.57	0.24	2641.00
Market share (Quarterly)	0.78	0.76	0.13	0.55	1.00	0.27	0.27	0.08	0.00	0.46
tyrosine kinase inhibitor (TKI)										
Price (USD per SU)	44.60	49.79	11.97	21.97	55.78	64.13	60.46	31.21	30.16	178.71

Volume (Thousand SUs)	1225.00	1247.00	388.78	172.72	1826.00	490.92	538.66	230.34	12.20	800.07
Market share	0.81	0.78	0.17	0.56	1	0.32	0.35	0.109	0.01	0.44
Class averages										
Price (USD per SU, quarterly)	44.19	47.75	20.07	15.31	85.33	60.65	50.76	33.39	19.48	178.71
Volume (Thousand SU, quarterly)	690.57	581.94	629.61	8.40	2553.00	306.29	223.26	280.04	0.48	1089.00
Market share (Quarterly)	0.84	0.88	0.17	0.44	1.00	0.28	0.28	0.14	0.00	0.56
enzyme replacement therapy										
Price (USD per SU)	1,765.62	1,696.67	325.18	1,179.28	2,128.61	1,526.20	1,530.92	69.36	1,403.74	1,697.07
Volume (Thousand SUs)	10.15	8.48	6.32	2.23	32.94	2.80	2.48	1.32	0.80	7.51
Market share	0.92	1.00	0.10	0.73	1.00	0.20	0.21	0.04	0.13	0.27
Class averages										
Price (USD per SU, quarterly)	1,480.00	1,461.49	449.30	729.03	2,295.74	1,661.81	1,611.75	230.12	1,268.62	2,199.92
Volume (Thousand SU, quarterly)	4.36	3.25	4.29	0.01	27.22	1.93	1.82	1.51	0.00	7.51
Market share (Quarterly)	0.83	1.00	0.22	0.05	1.00	0.34	0.26	0.20	0.00	0.95
PARP inhibitors										
Price (USD per SU)	20.18	14.86	10.39	11.56	44.77	83.57	92.57	28.86	46.19	120.92
Volume (Thousand SUs)	566.31	637.47	265.85	18.44	890.83	130.17	135.76	59.93	3.47	203.64
Market share	0.92	0.96	0.09	0.75	1	0.16	0.17	0.07	0.01	0.25
Class averages										
Price (USD per SU, quarterly)	20.58	14.26	11.59	9.33	45.61	87.26	92.49	22.82	35.01	130.66
Volume (Thousand SU, quarterly)	331.14	274.35	285.50	0.45	1378.00	108.23	107.91	70.61	0.00	282.76
Market share (Quarterly)	0.92	1.00	0.11	0.54	1.00	0.18	0.15	0.11	0.00	0.46
glucagon-like peptide-1 (GLP-1) receptor analogue										
Price (USD per SU)	66.17	100.92	36.68	24.70	101.13	43.80	45.76	18.47	19.69	78.12
Volume (Thousand SUs)	1242.00	777.47	1051.00	11.63	3617.00	1778.00	1753.00	1036.00	64.40	3559.00
Market share	0.23	0.09	0.33	0.02	1	0.92	0.94	0.08	0.41	0.98
Class averages										

Price (USD per SU, quarterly)	55.87	44.38	30.85	18.33	101.20	43.48	44.49	20.69	19.69	156.00
Volume (Thousand SU, quarterly)	67.81	46.82	64.02	0.03	271.32	946.09	606.52	953.54	0.09	4339.00
Market share (Quarterly)	0.31	0.14	0.34	0.00	1.00	0.87	0.90	0.12	0.08	1.00

Source: Authors based on IQVIA MIDAS™ database.

Germany

Table A B.7. Germany: summary statistics, 1997q4 and 2021q4

Therapeutic Class	First-in-class product					Follow-on products				
	Mean	**Median**	**S. Dev.**	**Min**	**Max**	**Mean**	**Median**	**S. Dev.**	**Min**	**Max**
direct oral anticoagulant										
Price (USD per SU, quarterly)	1.51	1.40	0.23	1.24	2.28	2.13	2.20	0.73	1.01	3.15
Volume (Thousand SU, quarterly)	141300.00	101600.00	136400.00	39.98	414500.00	165600.00	156900.00	126800.00	57.24	393400.00
Market share (Quarterly)	0.30	0.20	0.25	0.05	1	0.78	0.87	0.19	0.13	0.95
Class averages										
Price (USD per SU, quarterly)	1.45	1.21	0.50	0.93	2.51	2.18	2.13	1.09	0.91	5.89
Volume (Thousand SU, quarterly)	8246.00	3255.00	9067.00	0.02	35170.00	61630.00	27030.00	81890.00	0.08	393400.00
Market share (Quarterly)	0.42	0.34	0.30	0.04	1.00	0.68	0.77	0.26	0.01	0.97
insulin analogue										
Price (USD per SU, quarterly)	11.58	12.07	0.90	9.59	12.14	13.68	12.12	4.66	11.93	27.74
Volume (Thousand SU, quarterly)	3846.00	3783.00	2015.00	29.73	7763.00	1544.00	1542.00	744.27	64.07	2641.00
Market share (Quarterly)	0.80	0.73	0.14	0.65	1	0.29	0.32	0.08	0.03	0.35
Class averages										
Price (USD per SU, quarterly)	11.44	11.64	2.51	7.88	40.02	11.81	11.50	3.06	8.00	27.74
Volume (Thousand SU, quarterly)	1791.00	1797.00	1419.00	0.23	5137.00	761.43	717.66	640.57	0.24	2641.00
Market share (Quarterly)	0.78	0.76	0.13	0.55	1.00	0.27	0.27	0.08	0.00	0.46
tyrosine kinase inhibitor (TKI)										
Price (USD per SU, quarterly)	68.96	80.66	22.70	21.95	85.33	79.15	72.96	42.04	32.94	148.61

Volume (Thousand SU, quarterly)	1114.00	1009.00	445.92	103.97	1946.00	550.15	588.44	354.97	4.16	1089.00
Market share (Quarterly)	0.80	0.86	0.20	0.44	1	0.35	0.39	0.17	0.01	0.56
Class averages										
Price (USD per SU, quarterly)	44.19	47.75	20.07	15.31	85.33	60.65	50.76	33.39	19.48	178.71
Volume (Thousand SU, quarterly)	690.57	581.94	629.61	8.40	2553.00	306.29	223.26	280.04	0.48	1089.00
Market share (Quarterly)	0.84	0.88	0.17	0.44	1.00	0.28	0.28	0.14	0.00	0.56
enzyme replacement therapy										
Price (USD per SU, quarterly)	2,030.30	2,223.29	398.35	860.06	2,295.74	2,150.12	2,169.24	35.47	2,033.17	2,199.92
Volume (Thousand SU, quarterly)	3.45	3.81	1.59	0.00	6.44	1.30	1.35	0.59	0.16	2.41
Market share (Quarterly)	0.85	1	0.17	0.50	1	0.30	0.30	0.12	0.06	0.50
Class averages										
Price (USD per SU, quarterly)	1,480.00	1,461.49	449.30	729.03	2,295.74	1,661.81	1,611.75	230.12	1,268.62	2,199.92
Volume (Thousand SU, quarterly)	4.36	3.25	4.29	0.01	27.22	1.93	1.82	1.51	0.00	7.51
Market share (Quarterly)	0.83	1.00	0.22	0.05	1.00	0.34	0.26	0.20	0.00	0.95
PARP inhibitors										
Price (USD per SU, quarterly)	26.89	21.97	12.18	13.90	44.90	80.50	72.90	33.45	35.01	130.66
Volume (Thousand SU, quarterly)	799.39	737.27	390.00	19.13	1631.00	141.14	129.76	57.48	5.03	252.53
Market share (Quarterly)	0.92	0.87	0.07	0.84	1	0.13	0.13	0.03	0.01	0.16
Class averages										
Price (USD per SU, quarterly)	20.58	14.26	11.59	9.33	45.61	87.26	92.49	22.82	35.01	130.66
Volume (Thousand SU, quarterly)	331.14	274.35	285.50	0.45	1378.00	108.23	107.91	70.61	0.00	282.76
Market share (Quarterly)	0.92	1.00	0.11	0.54	1.00	0.18	0.15	0.11	0.00	0.46
glucagon-like peptide-1 (GLP-1) receptor analogue										
Price (USD per SU, quarterly)	62.23	45.94	25.45	42.86	101.20	45.38	50.62	24.91	20.83	156.00
Volume (Thousand SU, quarterly)	1191.00	624.89	1187.00	7.94	4374.00	1815.00	1677.00	1221.00	36.45	4339.00
Market share (Quarterly)	0.29	0.17	0.33	0.01	1	0.90	0.95	0.11	0.37	0.99

Class averages										
Price (USD per SU, quarterly)	55.87	44.38	30.85	18.33	101.20	43.48	44.49	20.69	19.69	156.00
Volume (Thousand SU, quarterly)	67.81	46.82	64.02	0.03	271.32	946.09	606.52	953.54	0.09	4339.00
Market share (Quarterly)	0.31	0.14	0.34	0.00	1.00	0.87	0.90	0.12	0.08	1.00

Source: Authors based on IQVIA MIDAS™ database.

Italy

Table A B.8. Italy: summary statistics, 1997q4 and 2021q4

Therapeutic Class	First-in-class product					Follow-on products				
	Mean	**Median**	**S. Dev.**	**Min**	**Max**	**Mean**	**Median**	**S. Dev.**	**Min**	**Max**
direct oral anticoagulant										
Price (USD per SU, quarterly)	1.64	1.28	0.54	1.21	2.41	2.47	2.39	1.21	1.21	5.08
Volume (Thousand SU, quarterly)	15190.00	7211.00	16800.00	0.03	48750.00	18780.00	17720.00	15800.00	0.08	45520.00
Market share (Quarterly)	0.49	0.44	0.24	0.21	1.00	0.60	0.69	0.20	0.03	0.79
Class averages										
Price (USD per SU, quarterly)	1.45	1.21	0.50	0.93	2.51	2.18	2.13	1.09	0.91	5.89
Volume (Thousand SU, quarterly)	8246.00	3255.00	9067.00	0.02	35170.00	61630.00	27030.00	81890.00	0.08	393400.00
Market share (Quarterly)	0.42	0.34	0.30	0.04	1.00	0.68	0.77	0.26	0.01	0.97
insulin analogue										
Price (USD per SU, quarterly)	12.33	12.15	0.58	11.58	13.55	11.67	10.95	2.67	9.99	19.30
Volume (Thousand SU, quarterly)	2107.00	2252.00	1332.00	2.95	4092.00	669.05	658.96	324.48	60.22	1245.00
Market share (Quarterly)	0.83	0.78	0.10	0.70	1.00	0.23	0.23	0.04	0.09	0.30
Class averages										
Price (USD per SU, quarterly)	11.44	11.64	2.51	7.88	40.02	11.81	11.50	3.06	8.00	27.74
Volume (Thousand SU, quarterly)	1791.00	1797.00	1419.00	0.23	5137.00	761.43	717.66	640.57	0.24	2641.00
Market share (Quarterly)	0.78	0.76	0.13	0.55	1.00	0.27	0.27	0.08	0.00	0.46

tyrosine kinase inhibitor (TKI)										
Price (USD per SU, quarterly)	19.35	19.13	0.86	18.17	21.65	72.41	54.63	40.59	32.52	152.73
Volume (Thousand SU, quarterly)	2060.00	2127.00	884.15	69.42	3251.00	409.16	470.38	229.58	3.45	743.32
Market share (Quarterly)	0.92	0.93	0.08	0.77	1.00	0.14	0.16	0.07	0.00	0.23
Class averages										
Price (USD per SU, quarterly)	44.19	47.75	20.07	15.31	85.33	60.65	50.76	33.39	19.48	178.71
Volume (Thousand SU, quarterly)	690.57	581.94	629.61	8.40	2553.00	306.29	223.26	280.04	0.48	1089.00
Market share (Quarterly)	0.84	0.88	0.17	0.44	1.00	0.28	0.28	0.14	0.00	0.56
enzyme replacement therapy										
Price (USD per SU, quarterly)	1,193.77	1,383.24	324.45	759.69	1,519.39	1,519.39	1,519.39	0.00	1,519.39	1,519.39
Volume (Thousand SU, quarterly)	7.47	8.24	2.68	0.91	10.87	1.94	1.86	0.70	0.41	3.19
Market share (Quarterly)	0.90	1.00	0.11	0.71	1.00	0.21	0.21	0.05	0.08	0.29
Class averages										
Price (USD per SU, quarterly)	1,480.00	1,461.49	449.30	729.03	2,295.74	1,661.81	1,611.75	230.12	1,268.62	2,199.92
Volume (Thousand SU, quarterly)	4.36	3.25	4.29	0.01	27.22	1.93	1.82	1.51	0.00	7.51
Market share (Quarterly)	0.83	1.00	0.22	0.05	1.00	0.34	0.26	0.20	0.00	0.95
PARP inhibitors										
Price (USD per SU, quarterly)	18.57	12.93	9.85	12.46	43.52	95.55	105.67	13.22	79.10	105.67
Volume (Thousand SU, quarterly)	481.30	584.70	225.12	13.55	732.43	96.95	99.37	30.85	11.43	130.57
Market share (Quarterly)	0.93	0.99	0.08	0.79	1.00	0.15	0.15	0.05	0.02	0.21
Class averages										
Price (USD per SU, quarterly)	20.58	14.26	11.59	9.33	45.61	87.26	92.49	22.82	35.01	130.66
Volume (Thousand SU, quarterly)	331.14	274.35	285.50	0.45	1378.00	108.23	107.91	70.61	0.00	282.76
Market share (Quarterly)	0.92	1.00	0.11	0.54	1.00	0.18	0.15	0.11	0.00	0.46
glucagon-like peptide-1 (GLP-1) receptor analogue										

Price (USD per SU, quarterly)	58.16	34.38	33.24	25.89	101.20	46.42	40.83	22.74	26.37	122.87
Volume (Thousand SU, quarterly)	648.99	316.42	742.95	1.33	3223.00	943.48	667.88	747.56	5.52	2965.00
Market share (Quarterly)	0.33	0.18	0.34	0.08	1.00	0.84	0.88	0.10	0.15	0.92
Class averages										
Price (USD per SU, quarterly)	55.87	44.38	30.85	18.33	101.20	43.48	44.49	20.69	19.69	156.00
Volume (Thousand SU, quarterly)	67.81	46.82	64.02	0.03	271.32	946.09	606.52	953.54	0.09	4339.00
Market share (Quarterly)	0.31	0.14	0.34	0.00	1.00	0.87	0.90	0.12	0.08	1.00

Authors based on IQVIA MIDAS™ database.

Norway

Table A B.9. Norway: summary statistics, 1997q4 and 2021q4

Therapeutic Class	First-in-class product					Follow-on products				
	Mean	**Median**	**S. Dev.**	**Min**	**Max**	**Mean**	**Median**	**S. Dev.**	**Min**	**Max**
direct oral anticoagulant										
Price (USD per SU, quarterly)	1.26	1.03	0.48	0.93	2.40	1.93	2.02	0.87	0.91	4.61
Volume (Thousand SU, quarterly)	8498.00	6116.00	8309.00	0.00	25610.00	9645.00	9882.00	7705.00	0.15	23660.00
Market share (Quarterly)	0.42	0.24	0.33	0.07	1	0.67	0.83	0.30	0.04	0.93
Class averages										
Price (USD per SU, quarterly)	1.45	1.21	0.50	0.93	2.51	2.18	2.13	1.09	0.91	5.89
Volume (Thousand SU, quarterly)	8246.00	3255.00	9067.00	0.02	35170.00	61630.00	27030.00	81890.00	0.08	393400.00
Market share (Quarterly)	0.42	0.34	0.30	0.04	1.00	0.68	0.77	0.26	0.01	0.97
insulin analogue										
Price (USD per SU, quarterly)	9.95	9.48	2.08	7.88	15.95	10.03	9.44	1.98	8.00	15.51
Volume (Thousand SU, quarterly)	112.10	118.39	78.87	0.23	263.13	55.00	60.64	26.11	0.24	95.00
Market share (Quarterly)	0.69	0.61	0.16	0.55	1	0.38	0.39	0.07	0.02	0.46
Class averages										
Price (USD per SU, quarterly)	11.44	11.64	2.51	7.88	40.02	11.81	11.50	3.06	8.00	27.74

Volume (Thousand SU, quarterly)	1791.00	1797.00	1419.00	0.23	5137.00	761.43	717.66	640.57	0.24	2641.00
Market share (Quarterly)	0.78	0.76	0.13	0.55	1.00	0.27	0.27	0.08	0.00	0.46
tyrosine kinase inhibitor (TKI)										
Price (USD per SU, quarterly)	39.54	45.33	12.68	16.19	52.28	47.25	49.53	25.95	19.48	131.75
Volume (Thousand SU, quarterly)	43.22	36.69	18.80	8.40	84.46	15.02	12.15	10.35	0.60	32.20
Market share (Quarterly)	0.87	0.91	0.14	0.61	1	0.24	0.23	0.12	0.02	0.40
Class averages										
Price (USD per SU, quarterly)	44.19	47.75	20.07	15.31	85.33	60.65	50.76	33.39	19.48	178.71
Volume (Thousand SU, quarterly)	690.57	581.94	629.61	8.40	2553.00	306.29	223.26	280.04	0.48	1089.00
Market share (Quarterly)	0.84	0.88	0.17	0.44	1.00	0.28	0.28	0.14	0.00	0.56
enzyme replacement therapy										
Price (USD per SU, quarterly)	1,211.85	1,298.20	199.23	770.20	1,480.53	1,456.13	1,408.05	113.23	1,340.60	1,708.27
Volume (Thousand SU, quarterly)	0.35	0.36	0.19	0.01	0.69	0.15	0.14	0.05	0.03	0.24
Market share (Quarterly)	0.86	1	0.17	0.49	1	0.29	0.26	0.11	0.10	0.51
Class averages										
Price (USD per SU, quarterly)	1,480.00	1,461.49	449.30	729.03	2,295.74	1,661.81	1,611.75	230.12	1,268.62	2,199.92
Volume (Thousand SU, quarterly)	4.36	3.25	4.29	0.01	27.22	1.93	1.82	1.51	0.00	7.51
Market share (Quarterly)	0.83	1.00	0.22	0.05	1.00	0.34	0.26	0.20	0.00	0.95
PARP inhibitors										
Price (USD per SU, quarterly)	21.91	17.74	12.34	10.58	40.58	109.31	109.31	0.00	109.31	109.31
Volume (Thousand SU, quarterly)	37.55	34.05	20.77	2.69	75.88	6.00	7.42	3.10	0.25	8.96
Market share (Quarterly)	0.98	1	0.05	0.88	1	0.09	0.10	0.04	0.01	0.12
Class averages										
Price (USD per SU, quarterly)	20.58	14.26	11.59	9.33	45.61	87.26	92.49	22.82	35.01	130.66
Volume (Thousand SU, quarterly)	331.14	274.35	285.50	0.45	1378.00	108.23	107.91	70.61	0.00	282.76
Market share (Quarterly)	0.92	1.00	0.11	0.54	1.00	0.18	0.15	0.11	0.00	0.46
glucagon-like peptide-1 (GLP-1) receptor analogue										
Price (USD per SU, quarterly)	47.16	30.36	28.39	24.23	91.96	41.78	36.80	20.53	21.50	103.60

Volume (Thousand SU, quarterly)	64.80	48.67	62.60	0.03	243.28	95.38	84.10	58.45	0.09	235.75
Market share (Quarterly)	0.29	0.13	0.35	0.03	1	0.89	0.91	0.10	0.08	0.97
Class averages										
Price (USD per SU, quarterly)	55.87	44.38	30.85	18.33	101.20	43.48	44.49	20.69	19.69	156.00
Volume (Thousand SU, quarterly)	67.81	46.82	64.02	0.03	271.32	946.09	606.52	953.54	0.09	4339.00
Market share (Quarterly)	0.31	0.14	0.34	0.00	1.00	0.87	0.90	0.12	0.08	1.00

Source: Authors based on IQVIA MIDAS™ database.

Spain

Table A B.10. Spain: summary statistics, 1997q4 and 2021q4

Therapeutic Class	First-in-class product					Follow-on products				
	Mean	**Median**	**S. Dev.**	**Min**	**Max**	**Mean**	**Median**	**S. Dev.**	**Min**	**Max**
direct oral anticoagulant										
Price (USD per SU, quarterly)	1.33	1.11	0.38	1.11	2.02	2.12	2.13	1.00	1.11	4.65
Volume (Thousand SU, quarterly)	30050.00	20020.00	29160.00	24.73	91740.00	29550.00	27030.00	24600.00	1.88	76200.00
Market share (Quarterly)	0.51	0.41	0.29	0.17	1	0.59	0.72	0.26	0.01	0.83
Class averages										
Price (USD per SU, quarterly)	1.45	1.21	0.50	0.93	2.51	2.18	2.13	1.09	0.91	5.89
Volume (Thousand SU, quarterly)	8246.00	3255.00	9067.00	0.02	35170.00	61630.00	27030.00	81890.00	0.08	393400.00
Market share (Quarterly)	0.42	0.34	0.30	0.04	1.00	0.68	0.77	0.26	0.01	0.97
insulin analogue										
Price (USD per SU, quarterly)	12.85	11.38	5.79	11.32	40.02	11.50	11.50	0.00	11.50	11.50
Volume (Thousand SU, quarterly)	3042.00	3416.00	1626.00	9.43	5336.00	904.98	1046.00	331.78	60.05	1215.00
Market share (Quarterly)	0.77	0.74	0.10	0.67	1	0.26	0.27	0.05	0.08	0.33
Class averages										
Price (USD per SU, quarterly)	11.44	11.64	2.51	7.88	40.02	11.81	11.50	3.06	8.00	27.74
Volume (Thousand SU, quarterly)	1791.00	1797.00	1419.00	0.23	5137.00	761.43	717.66	640.57	0.24	2641.00

Market share (Quarterly)	0.78	0.76	0.13	0.55	1.00	0.27	0.27	0.08	0.00	0.46
tyrosine kinase inhibitor (TKI)										
Price (USD per SU, quarterly)	55.65	63.89	16.20	23.02	68.35	51.78	63.64	17.34	28.77	73.42
Volume (Thousand SU, quarterly)	633.19	566.30	239.99	241.42	1055.00	218.09	204.40	142.24	13.82	416.65
Market share (Quarterly)	0.82	0.81	0.16	0.60	1	0.28	0.30	0.11	0.02	0.40
Class averages										
Price (USD per SU, quarterly)	44.19	47.75	20.07	15.31	85.33	60.65	50.76	33.39	19.48	178.71
Volume (Thousand SU, quarterly)	690.57	581.94	629.61	8.40	2553.00	306.29	223.26	280.04	0.48	1089.00
Market share (Quarterly)	0.84	0.88	0.17	0.44	1.00	0.28	0.28	0.14	0.00	0.56
enzyme replacement therapy										
Price (USD per SU, quarterly)	1,370.48	1,666.98	417.57	846.34	1,766.89	1,659.27	1,611.75	70.46	1,611.75	1,766.64
Volume (Thousand SU, quarterly)	8.77	7.67	3.66	2.08	16.73	3.11	3.41	1.10	0.40	4.75
Market share (Quarterly)	0.79	1	0.24	0.36	1	0.44	0.49	0.12	0.09	0.64
Class averages										
Price (USD per SU, quarterly)	1,480.00	1,461.49	449.30	729.03	2,295.74	1,661.81	1,611.75	230.12	1,268.62	2,199.92
Volume (Thousand SU, quarterly)	4.36	3.25	4.29	0.01	27.22	1.93	1.82	1.51	0.00	7.51
Market share (Quarterly)	0.83	1.00	0.22	0.05	1.00	0.34	0.26	0.20	0.00	0.95
PARP inhibitors										
Price (USD per SU, quarterly)	22.08	12.72	11.99	12.72	42.27	90.32	101.69	15.16	71.37	101.69
Volume (Thousand SU, quarterly)	386.03	397.12	139.50	64.18	617.04	87.23	90.46	35.61	11.09	134.73
Market share (Quarterly)	0.94	1	0.09	0.77	1	0.17	0.17	0.05	0.03	0.23
Class averages										
Price (USD per SU, quarterly)	20.58	14.26	11.59	9.33	45.61	87.26	92.49	22.82	35.01	130.66
Volume (Thousand SU, quarterly)	331.14	274.35	285.50	0.45	1378.00	108.23	107.91	70.61	0.00	282.76
Market share (Quarterly)	0.92	1.00	0.11	0.54	1.00	0.18	0.15	0.11	0.00	0.46
glucagon-like peptide-1 (GLP-1) receptor analogue										
Price (USD per SU, quarterly)	50.37	30.00	33.68	18.33	96.21	45.52	45.62	21.06	23.60	113.47

Volume (Thousand SU, quarterly)	583.53	422.29	544.06	1.36	1879.00	823.82	805.23	484.85	4.95	1806.00
Market share (Quarterly)	0.36	0.22	0.35	0.04	1	0.83	0.85	0.11	0.14	0.96
Class averages										
Price (USD per SU, quarterly)	55.87	44.38	30.85	18.33	101.20	43.48	44.49	20.69	19.69	156.00
Volume (Thousand SU, quarterly)	67.81	46.82	64.02	0.03	271.32	946.09	606.52	953.54	0.09	4339.00
Market share (Quarterly)	0.31	0.14	0.34	0.00	1.00	0.87	0.90	0.12	0.08	1.00

Source: Authors based on IQVIA MIDAS™ database.

Sweden

Table A B.11. Sweden: summary statistics, 1997q4 and 2021q4

Therapeutic Class	First-in-class product					Follow-on products				
	Mean	**Median**	**S. Dev.**	**Min**	**Max**	**Mean**	**Median**	**S. Dev.**	**Min**	**Max**
direct oral anticoagulant										
Price (USD per SU, quarterly)	1.41	1.09	0.46	1.09	2.24	2.22	2.18	1.23	1.09	5.49
Volume (Thousand SU, quarterly)	15190.00	7211.00	16800.00	0.03	48750.00	18780.00	17720.00	15800.00	0.08	45520.00
Market share (Quarterly)	0.44	0.27	0.37	0.07	1	0.69	0.88	0.32	0.01	0.93
Class averages										
Price (USD per SU, quarterly)	1.45	1.21	0.50	0.93	2.51	2.18	2.13	1.09	0.91	5.89
Volume (Thousand SU, quarterly)	8246.00	3255.00	9067.00	0.02	35170.00	61630.00	27030.00	81890.00	0.08	393400.00
Market share (Quarterly)	0.42	0.34	0.30	0.04	1.00	0.68	0.77	0.26	0.01	0.97
insulin analogue										
Price (USD per SU, quarterly)	11.59	11.79	0.44	10.65	11.84	12.37	11.72	1.89	10.93	17.26
Volume (Thousand SU, quarterly)	568.13	657.29	186.02	26.70	797.88	152.70	171.66	57.54	22.37	225.13
Market share (Quarterly)	0.81	0.76	0.09	0.72	1	0.23	0.25	0.06	0.06	0.28
Class averages										
Price (USD per SU, quarterly)	11.44	11.64	2.51	7.88	40.02	11.81	11.50	3.06	8.00	27.74

Volume (Thousand SU, quarterly)	1791.00	1797.00	1419.00	0.23	5137.00	761.43	717.66	640.57	0.24	2641.00
Market share (Quarterly)	0.78	0.76	0.13	0.55	1.00	0.27	0.27	0.08	0.00	0.46
tyrosine kinase inhibitor (TKI)										
Price (USD per SU, quarterly)	44.62	50.08	12.43	21.10	55.15	61.83	51.03	31.09	26.06	112.81
Volume (Thousand SU, quarterly)	139.83	133.62	48.91	22.08	223.70	56.33	66.65	31.83	0.48	94.50
Market share (Quarterly)	0.82	0.84	0.17	0.56	1	0.30	0.36	0.13	0.01	0.44
Class averages										
Price (USD per SU, quarterly)	44.19	47.75	20.07	15.31	85.33	60.65	50.76	33.39	19.48	178.71
Volume (Thousand SU, quarterly)	690.57	581.94	629.61	8.40	2553.00	306.29	223.26	280.04	0.48	1089.00
Market share (Quarterly)	0.84	0.88	0.17	0.44	1.00	0.28	0.28	0.14	0.00	0.56
enzyme replacement therapy										
Price (USD per SU, quarterly)	1,736.38	1,694.20	68.19	1,528.01	1,831.57	1,637.03	1,648.40	81.39	1,326.18	1,739.92
Volume (Thousand SU, quarterly)	1.58	1.54	0.48	0.48	2.44	0.68	0.29	0.77	0.00	2.29
Market share (Quarterly)	0.70	0.83	0.33	0.05	1	0.34	0.19	0.33	0	0.95
Class averages										
Price (USD per SU, quarterly)	1,480.00	1,461.49	449.30	729.03	2,295.74	1,661.81	1,611.75	230.12	1,268.62	2,199.92
Volume (Thousand SU, quarterly)	4.36	3.25	4.29	0.01	27.22	1.93	1.82	1.51	0.00	7.51
Market share (Quarterly)	0.83	1.00	0.22	0.05	1.00	0.34	0.26	0.20	0.00	0.95
PARP inhibitors										
Price (USD per SU, quarterly)	14.85	11.48	5.99	11.44	32.24	91.74	87.49	9.46	87.48	111.29
Volume (Thousand SU, quarterly)	78.73	72.41	42.54	2.69	139.22	10.71	9.97	10.90	0.00	31.72
Market share (Quarterly)	0.96	1	0.07	0.76	1	0.09	0.09	0.09	0	0.25
Class averages										
Price (USD per SU, quarterly)	20.58	14.26	11.59	9.33	45.61	87.26	92.49	22.82	35.01	130.66
Volume (Thousand SU, quarterly)	331.14	274.35	285.50	0.45	1378.00	108.23	107.91	70.61	0.00	282.76
Market share (Quarterly)	0.92	1.00	0.11	0.54	1.00	0.18	0.15	0.11	0.00	0.46

glucagon-like peptide-1 (GLP-1) receptor analogue										
Price (USD per SU, quarterly)	52.65	30.43	32.24	27.19	98.00	44.46	32.84	19.63	27.22	107.01
Volume (Thousand SU, quarterly)	154.12	79.14	191.45	0.03	837.01	261.09	214.66	213.79	1.21	834.13
Market share (Quarterly)	0.26	0.10	0.37	0.003	1	0.94	0.96	0.07	0.3	1.00
Class averages										
Price (USD per SU, quarterly)	55.87	44.38	30.85	18.33	101.20	43.48	44.49	20.69	19.69	156.00
Volume (Thousand SU, quarterly)	67.81	46.82	64.02	0.03	271.32	946.09	606.52	953.54	0.09	4339.00
Market share (Quarterly)	0.31	0.14	0.34	0.00	1.00	0.87	0.90	0.12	0.08	1.00

Source: Authors based on IQVIA MIDAS™ database.

United Kingdom

Table A B.12. United Kingdom: summary statistics, 1997q4 and 2021q4

Therapeutic Class	First-in-class product					Follow-on products				
	Mean	**Median**	**S. Dev.**	**Min**	**Max**	**Mean**	**Median**	**S. Dev.**	**Min**	**Max**
direct oral anticoagulant										
Price (USD per SU, quarterly)	1.48	1.30	0.59	1.00	2.50	2.22	2.10	1.15	1.12	5.31
Volume (Thousand SU, quarterly)	58710.00	11170.00	70720.00	0.02	201400.00	75200.00	69740.00	68870.00	1.99	194400.00
Market share (Quarterly)	0.33	0.35	0.26	0.035	1	0.77	0.90	0.22	0.08	0.97
Class averages										
Price (USD per SU, quarterly)	1.45	1.21	0.50	0.93	2.51	2.18	2.13	1.09	0.91	5.89
Volume (Thousand SU, quarterly)	8246.00	3255.00	9067.00	0.02	35170.00	61630.00	27030.00	81890.00	0.08	393400.00
Market share (Quarterly)	0.42	0.34	0.30	0.04	1.00	0.68	0.77	0.26	0.01	0.97
insulin analogue										
Price (USD per SU, quarterly)	9.95	9.94	0.16	9.65	10.23	11.57	9.93	4.43	9.20	24.61
Volume (Thousand SU, quarterly)	3078.00	3671.00	1333.00	45.09	4417.00	1146.00	1371.00	433.83	2.40	1536.00
Market share (Quarterly)	0.75	0.69	0.13	0.65	1	0.30	0.34	0.08	0.002	0.35
Class averages										

Price (USD per SU, quarterly)	11.44	11.64	2.51	7.88	40.02	11.81	11.50	3.06	8.00	27.74
Volume (Thousand SU, quarterly)	1791.00	1797.00	1419.00	0.23	5137.00	761.43	717.66	640.57	0.24	2641.00
Market share (Quarterly)	0.78	0.76	0.13	0.55	1.00	0.27	0.27	0.08	0.00	0.46
tyrosine kinase inhibitor (TKI)										
Price (USD per SU, quarterly)	36.60	40.23	12.00	15.31	52.30	43.52	48.91	17.74	25.61	146.23
Volume (Thousand SU, quarterly)	733.95	756.44	252.37	93.36	1243.00	321.21	332.02	172.28	1.34	576.23
Market share (Quarterly)	0.81	0.81	0.18	0.54	1	0.33	0.38	0.13	0.003	0.46
Class averages										
Price (USD per SU, quarterly)	44.19	47.75	20.07	15.31	85.33	60.65	50.76	33.39	19.48	178.71
Volume (Thousand SU, quarterly)	690.57	581.94	629.61	8.40	2553.00	306.29	223.26	280.04	0.48	1089.00
Market share (Quarterly)	0.84	0.88	0.17	0.44	1.00	0.28	0.28	0.14	0.00	0.56
enzyme replacement therapy										
Price (USD per SU, quarterly)	1,137.71	1,169.38	189.40	729.03	1,361.99	1,653.78	1,663.59	62.46	1,268.62	1,664.30
Volume (Thousand SU, quarterly)	3.58	3.02	2.83	0.32	9.32	3.84	3.96	1.00	1.67	5.50
Market share (Quarterly)	0.74	1	0.30	0.27	1	0.59	0.59	0.05	0.45	0.73
Class averages										
Price (USD per SU, quarterly)	1,480.00	1,461.49	449.30	729.03	2,295.74	1,661.81	1,611.75	230.12	1,268.62	2,199.92
Volume (Thousand SU, quarterly)	4.36	3.25	4.29	0.01	27.22	1.93	1.82	1.51	0.00	7.51
Market share (Quarterly)	0.83	1.00	0.22	0.05	1.00	0.34	0.26	0.20	0.00	0.95
PARP inhibitors										
Price (USD per SU, quarterly)	20.03	10.95	14.28	9.33	45.61	82.68	94.48	14.21	43.78	94.91
Volume (Thousand SU, quarterly)	271.49	246.67	183.03	0.45	612.88	142.90	145.42	80.96	0.28	282.76
Market share (Quarterly)	0.82	0.90	0.19	0.54	1	0.32	0.35	0.13	0.001	0.46
Class averages										
Price (USD per SU, quarterly)	20.58	14.26	11.59	9.33	45.61	87.26	92.49	22.82	35.01	130.66
Volume (Thousand SU, quarterly)	331.14	274.35	285.50	0.45	1378.00	108.23	107.91	70.61	0.00	282.76

Market share (Quarterly)	0.92	1.00	0.11	0.54	1.00	0.18	0.15	0.11	0.00	0.46
glucagon-like peptide-1 (GLP-1) receptor analogue										
Price (USD per SU, quarterly)	54.63	46.52	21.72	31.58	80.50	38.14	34.35	15.78	20.88	86.42
Volume (Thousand SU, quarterly)	683.13	530.63	634.30	0.41	2730.00	953.62	806.39	646.84	13.96	2661.00
Market share (Quarterly)	0.39	0.30	0.31	0.03	1	0.81	0.84	0.15	0.16	0.98
Class averages										
Price (USD per SU, quarterly)	55.87	44.38	30.85	18.33	101.20	43.48	44.49	20.69	19.69	156.00
Volume (Thousand SU, quarterly)	67.81	46.82	64.02	0.03	271.32	946.09	606.52	953.54	0.09	4339.00
Market share (Quarterly)	0.31	0.14	0.34	0.00	1.00	0.87	0.90	0.12	0.08	1.00

Source: Authors based on IQVIA MIDAS™ database.

Estimation results from the regression analyses

Table A B.13 shows the estimation results of Model 1 and 2, where three different specifications of a time trend have been estimated. Table A B.14 shows the estimation results of Model 1 and 2, this time for a retail and hospital sub-sample respectively. Finally Table A B.15 shows the estimation results for Model 3, where the same time trend specifications as for Model 1 and 2 are considered.

Table A B.13. Estimation results for Models 1 and 2 as described in Table A B.5.

	Model 1			Model 2		
	(A)	(B)	(C)	(A)	(B)	(C)
Follow-on drug 1	0.297	0.296	0.288	0.405	0.404	0.402
	(0.192)	(0.194)	(0.203)	(0.275)	(0.274)	(0.286)
Follow-on drug 2	0.449*	0.434	0.449	0.297	0.280	0.293
	(0.215)	(0.218)	(0.226)	(0.181)	(0.184)	(0.191)
Follow-on drug 3	-0.230	-0.258*	-0.263	-0.127	-0.157	-0.167
	(0.120)	(0.127)	(0.134)	(0.140)	(0.143)	(0.152)
Follow-on drug 4	-0.413**	-0.413**	-0.423**	-0.317	-0.316	-0.325
	(0.152)	(0.148)	(0.156)	(0.184)	(0.180)	(0.191)
Follow-on drug 5	-0.453**	-0.432**	-0.527*	-0.420*	-0.398*	-0.499*
	(0.149)	(0.168)	(0.219)	(0.165)	(0.178)	(0.217)
t		0.0154***			0.0165***	
		(0.00297)			(0.00298)	
France X time trend *t*			0.00947***			0.0106***
			(0.00185)			(0.00173)
Germany X time trend *t*			0.0241***			0.0244***
			(0.00264)			(0.00249)
Italy X time trend *t*			0.0129*			0.0139**
			(0.00512)			(0.00467)
Norway X time trend *t*			0.0116**			0.0131**

			(0.00391)			(0.00365)
Spain X time trend *t*			0.0217***			0.0212***
			(0.00257)			(0.00250)
Sweden X time trend *t*			0.0157***			0.0174***
			(0.00363)			(0.00332)
UK X time trend *t*			0.0154***			0.0200***
			(0.00189)			(0.00231)
Constant	1.002***	0.979***	0.988***	1.002***	0.978***	0.987***
	(0)	(0.00446)	(0.00278)	(8.59e-07)	(0.00447)	(0.00260)
Country fixed effect (FE)	Yes	Yes	Yes	Yes	Yes	Yes
Year FE	Yes	Yes	Yes	Yes	Yes	Yes
Therapeutic class FE	Yes	Yes	Yes	Yes	Yes	Yes
Observations	2,355	2,355	2,355	2,355	2,355	2,355
R-squared	0.680	0.692	0.711	0.676	0.690	0.706

Note: Robust standard errors in parentheses *** p<0.01, ** p<0.05, * p<0.1. Standard Errors are clustered at country, therapeutic class and year level.
Source: Authors

Table A B.14. Robustness checks for estimation results for Models 1 and 2 as described in Table A B.5.

Results from estimations of Model 1 and 2, disaggregated according to sector and excluding the 4th and 5th follow-on drugs.

	Hospital Sector		Retail Sector		Excluding 4th and 5th follow-on products	
	Model 1	Model 2	Model 1	Model 2	Model 1	Model 2
Follow-on drug 1	0.240	0.461	0.0248	0.0438	0.282	0.397
	(0.229)	(0.434)	(0.113)	(0.163)	(0.203)	(0.284)
Follow-on drug 2	0.264	0.0629	0.404*	0.309	0.445	0.289
	(0.326)	(0.216)	(0.201)	(0.161)	(0.223)	(0.185)
Follow-on drug 3	-0.381*	-0.238	-0.164	-0.0776	-0.265	-0.171
	(0.179)	(0.168)	(0.120)	(0.103)	(0.136)	(0.156)
Follow-on drug 4	-0.565*	-0.348	-0.233	-0.164	-	-
	(0.276)	(0.285)	(0.143)	(0.191)	-	-
Follow-on drug 5	-1.020	-0.945	-0.425	-0.359	-	-
	(0.549)	(0.528)	(0.250)	(0.263)	-	-
France X time trend *t*	0.0389**	0.0348*	0.0161***	0.0146***	0.00941***	0.0107***
	(0.0148)	(0.0138)	(0.00357)	(0.00202)	(0.00190)	(0.00170)
Germany X time trend *t*	0.0562**	0.0525**	0.0282***	0.0267***	0.0249***	0.0253***
	(0.0175)	(0.0155)	(0.00244)	(0.00168)	(0.00249)	(0.00235)
Italy X time trend *t*	0.0445**	0.0426**	0.0133*	0.0151**	0.0129*	0.0141**
	(0.0155)	(0.0134)	(0.00524)	(0.00540)	(0.00512)	(0.00466)
Norway X time trend *t*	0.0434*	0.0418**	0.0177**	0.0173**	0.0116**	0.0129**
	(0.0169)	(0.0150)	(0.00587)	(0.00507)	(0.00374)	(0.00351)
Spain X time trend *t*	0.0517**	0.0486***	0.0242***	0.0230***	0.0214***	0.0209***
	(0.0146)	(0.0120)	(0.00417)	(0.00395)	(0.00300)	(0.00292)
Sweden X time trend *t*	0.0429*	0.0448*	0.0251***	0.0241***	0.0161***	0.0180***
	(0.0206)	(0.0183)	(0.00292)	(0.00200)	(0.00331)	(0.00293)
UK X time trend *t*	0.0469**	0.0489**	0.0235**	0.0247**	0.0149***	0.0200***

	(0.0180)	(0.0143)	(0.00684)	(0.00642)	(0.00199)	(0.00250)
Constant	0.944***	0.950***	1.619***	1.592***	0.988***	0.986***
	(0.0222)	(0.0207)	(0.233)	(0.214)	(0.00285)	(0.00255)
Country fixed effect (FE)	Yes	Yes	Yes	Yes	Yes	Yes
Year FE	Yes	Yes	Yes	Yes	Yes	Yes
Therapeutic class FE	Yes	Yes	Yes	Yes	Yes	Yes
Observations	2,326	2,332	1,636	1,653	2,242	2,242
R-squared	0.380	0.398	0.759	0.755	0.698	0.694

Note: Robust standard errors in parentheses *** p<0.01, ** p<0.05, * p<0.1. Standard Errors are clustered at country, therapeutic class and year level.
Source: Authors

Table A B.15. Model 3 as described in Table A B.5.

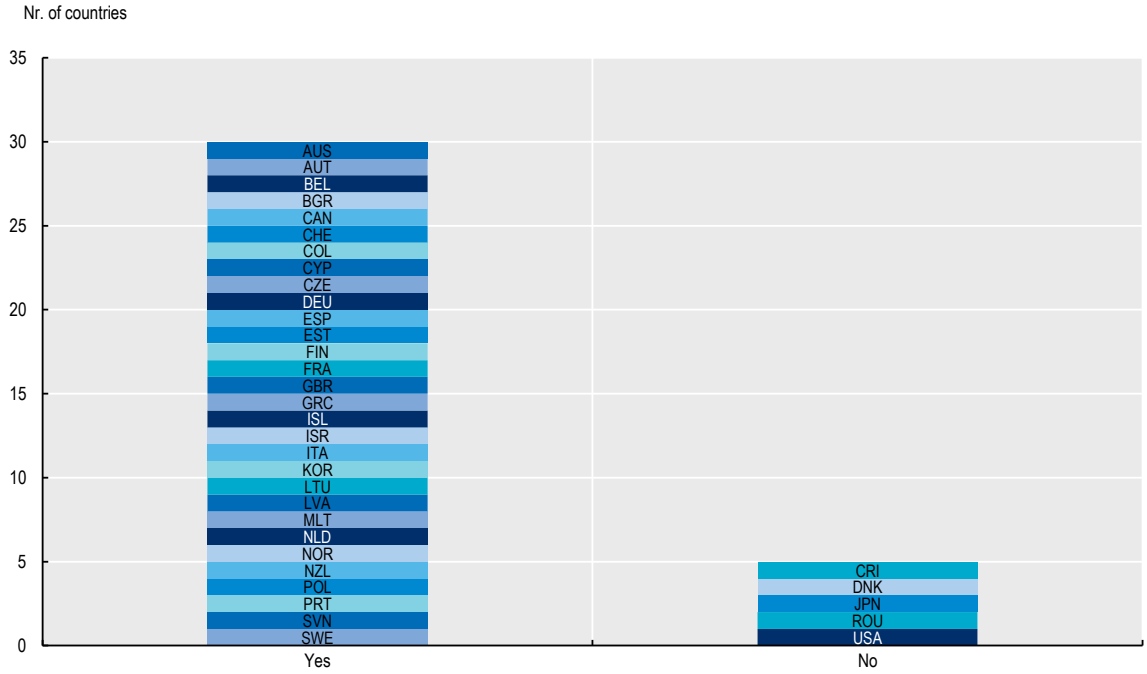
	Volume			Sales		
	(A)	(B)	(C)	(A)	(B)	(C)
Log number of competitors in the class	-0.0346	-0.0331	-0.0276	-0.0407	-0.0394	-0.0336
	(0.0795)	(0.0830)	(0.0824)	(0.0660)	(0.0712)	(0.0690)
time trend t		-0.00120			-0.00104	
		(0.00140)			(0.00137)	
France X time trend *t*			-0.00129			-0.00124
			(0.00142)			(0.00146)
Germany X time trend *t*			-0.00160			-0.00135
			(0.00142)			(0.00142)
Italy X time trend *t*			-0.000979			-0.000791
			(0.00121)			(0.00126)
Norway X time trend *t*			-0.00117			-0.000912
			(0.00144)			(0.00147)
Spain X time trend *t*			-0.00164			-0.00145
			(0.00143)			(0.00153)
Sweden X time trend *t*			-0.00172			-0.00151
			(0.00141)			(0.00148)
UK X time trend *t*			-0.00131			-0.00108
			(0.00130)			(0.00134)
Constant	0.616***	0.542***	0.519***	0.615***	0.550***	0.531***
	(0.107)	(0.0882)	(0.0497)	(0.107)	(0.0744)	(0.0392)
Country fixed effect (FE)	Yes	Yes	Yes	Yes	Yes	Yes
Product fixed effect	Yes	Yes	Yes	Yes	Yes	Yes
Year fixed effects	Yes	Yes	Yes	Yes	Yes	Yes
Observations	5,154	5,154	5,154	5,154	5,154	5,154
R-squared	0.142	0.142	0.140	0.136	0.136	0.134

Note: Robust standard errors in parentheses *** p<0.01, ** p<0.05, * p<0.1. Standard Errors are clustered at country, therapeutic class and year level.
Source: Authors

Annex C. Questionnaire and Survey results

Figure A C.1. Assessment of comparative effectiveness of therapeutic alternatives for a given indication

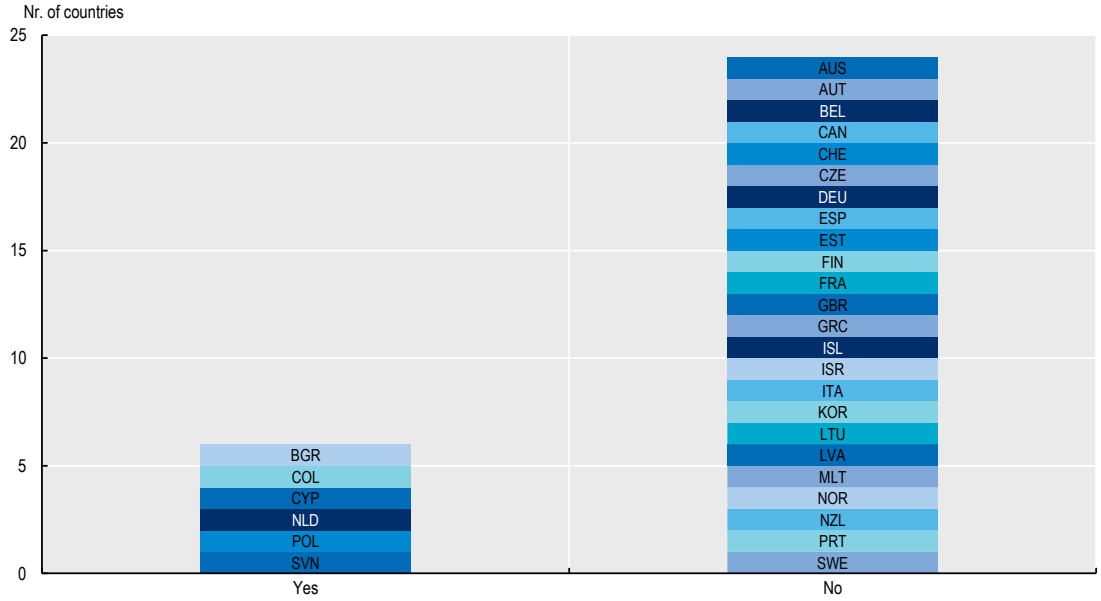
Question B1: Is there an official (or at least widely recognised) process for the assessment of comparative effectiveness of therapeutic alternatives for a given indication?



Note: 1. Comparative effectiveness assessments are only used in the outpatient sector in Austria.
Source: OECD survey on Price Transparency/On-patent competition 2022.

Figure A C.2. Assessment of effectiveness of therapeutic alternatives limited to the same therapeutic class

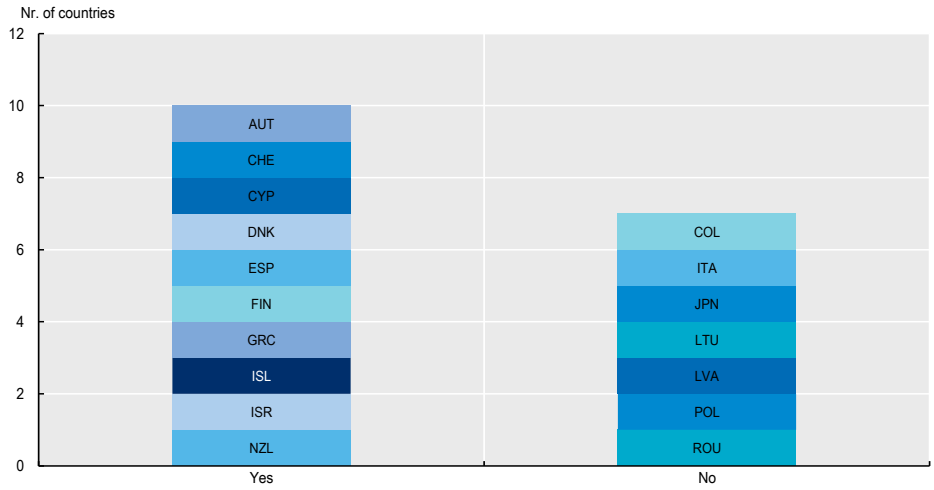
Question B1.1: If you answered "Yes" to B1, is this limited to alternatives within the same therapeutic class?



Source: OECD survey on Price Transparency/On-patent competition 2022.

Figure A C.3. Differential coverage or reimbursement as a mechanism to encourage prescribing and the use of certain products

Question B2. Where products found to have similar effectiveness have different coverage/reimbursement amounts, is this intended as a mechanism to encourage prescribing and the use of certain products over others?



Source: OECD survey on Price Transparency/On-patent competition 2022.

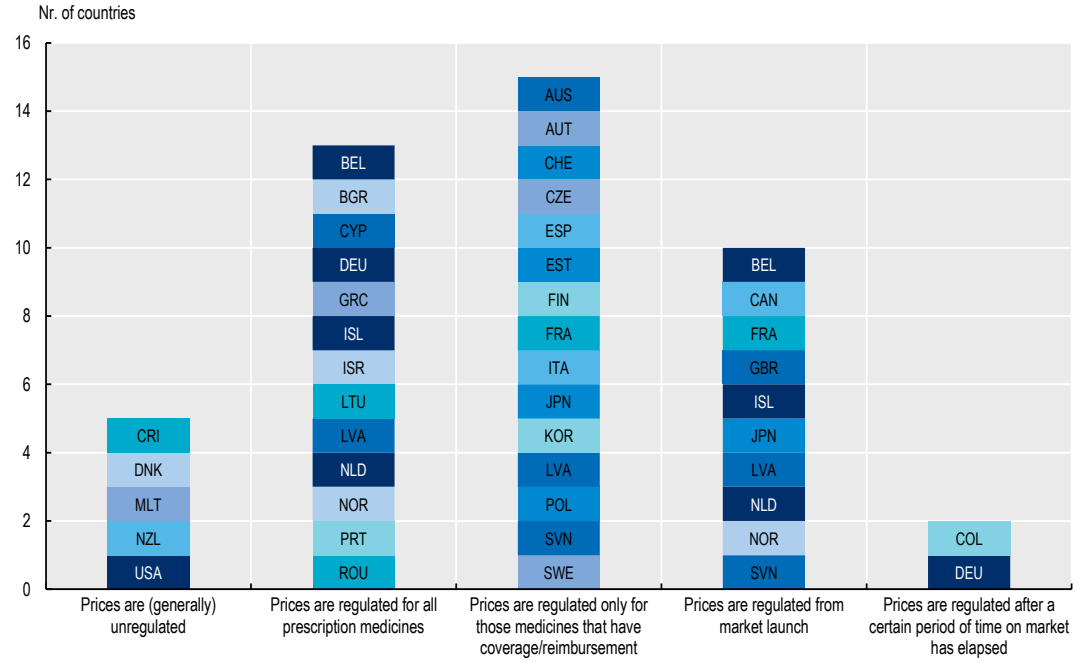
Figure A C.4. Ranking according to cost or cost-effectiveness in treatment/prescribing guidelines

Question B3: Are products ranked according to cost or cost-effectiveness in treatment/prescribing guidelines?

Source: OECD survey on Price Transparency/On-patent competition 2022.

Figure A C.5. Price regulation of medicines across countries

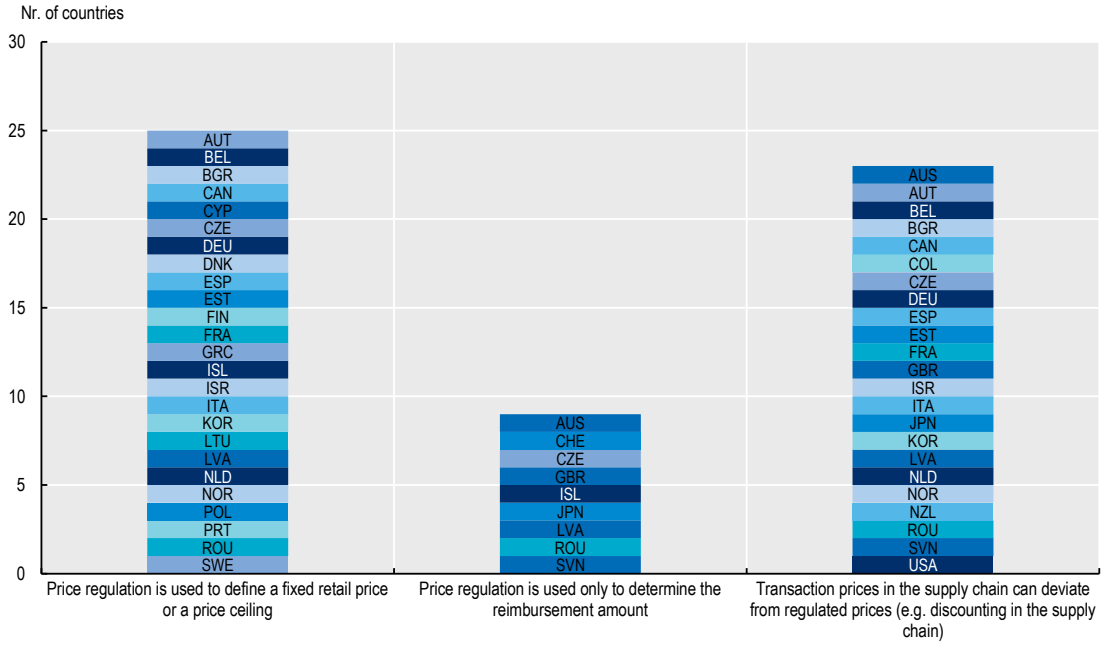
Question B6: Concerning price regulation of medicines, which of the following statements are applicable?



Source: OECD survey on Price Transparency/On-patent competition 2022.

Figure A C.6. Purpose of price regulations of medicines

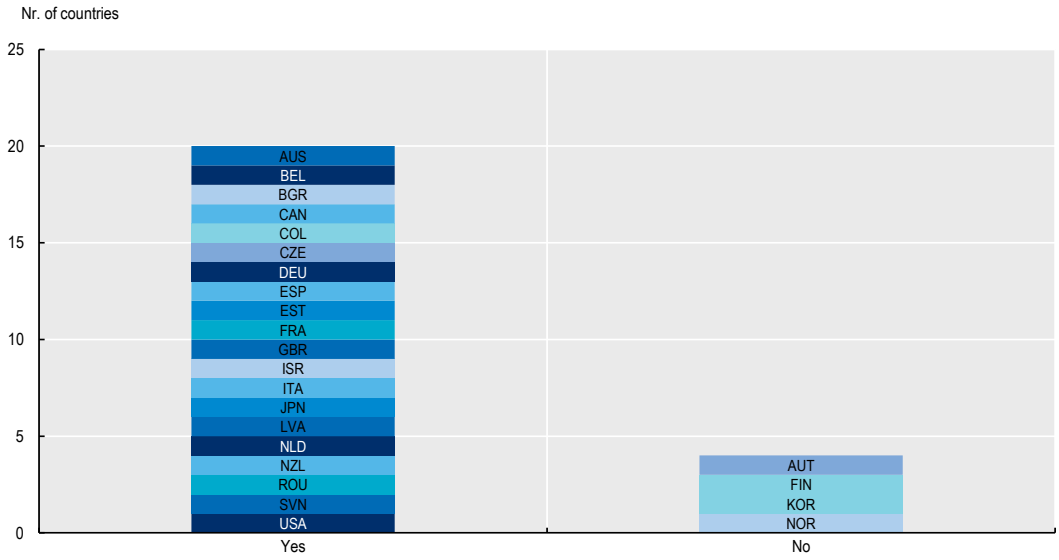
Question B7.1: Concerning price regulation of medicines, which of the following statements are applicable? Please, select all options that apply.



Source: OECD survey on Price Transparency/On-patent competition 2022.

Figure A C.7. Ability of buyers to buy medicines at prices below regulated prices and retain the difference between the transaction prices and the coverage/reimbursement amounts

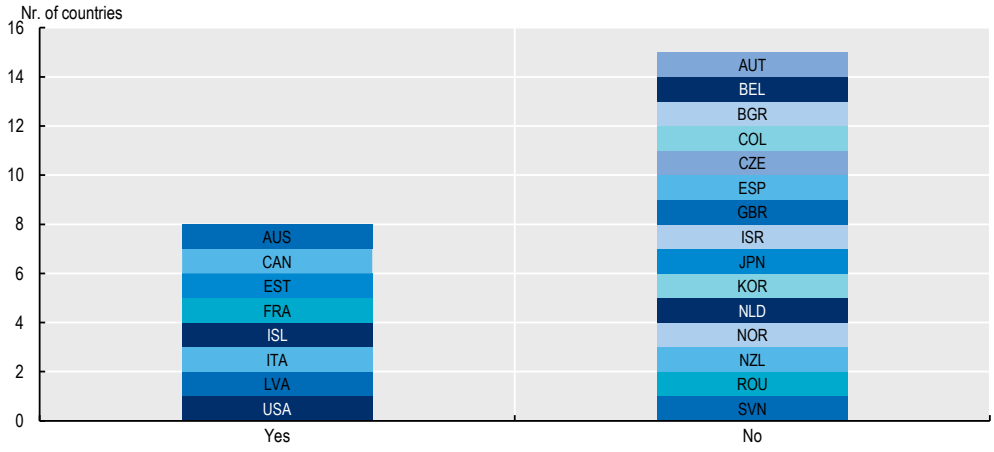
Question B7.2: If you answered that "transaction prices in the supply chain can deviate from regulated prices" in B7, please answer the following question. Are buyers able to buy medicines at prices below regulated prices and retain the difference between the transaction prices and the coverage/reimbursement amounts? Please, select one the options.



Source: OECD survey on Price Transparency/On-patent competition 2022.

Figure A C.8. Requirements for the disclosure of actual transaction prices within the supply chain

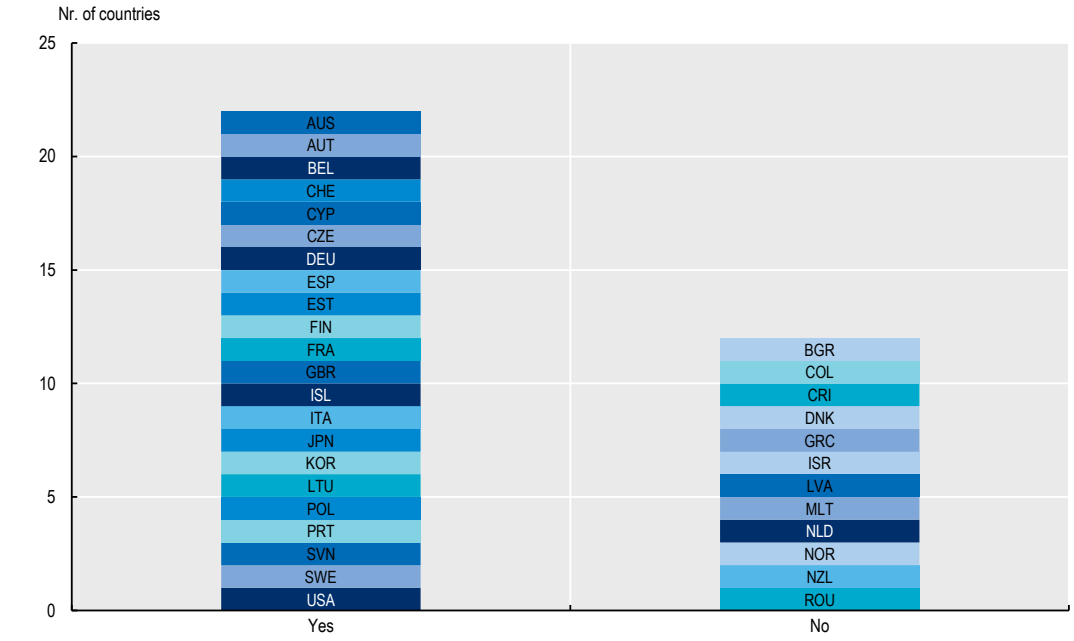
Question B7.3: If you answered that "transaction prices in the supply chain can deviate from regulated prices" in B7, please answer the following question. Are there any requirements for the disclosure of actual transaction prices within the supply chain? Please, select one the options.



Source: OECD survey on Price Transparency/On-patent competition 2022.

Figure A C.9. Pricing arrangements take into account the prices of therapeutic alternatives

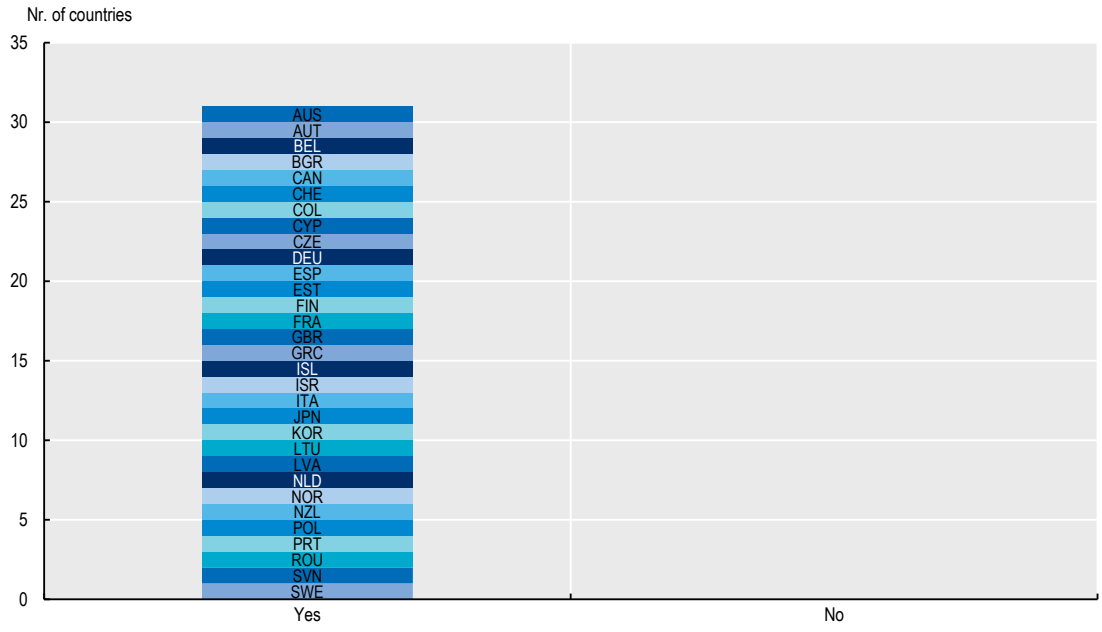
Question B8: Do pricing arrangements take into account the prices of therapeutic alternatives?



Source: OECD survey on Price Transparency/On-patent competition 2022.

Figure A C.10. Modifying regulated price once it has been determined

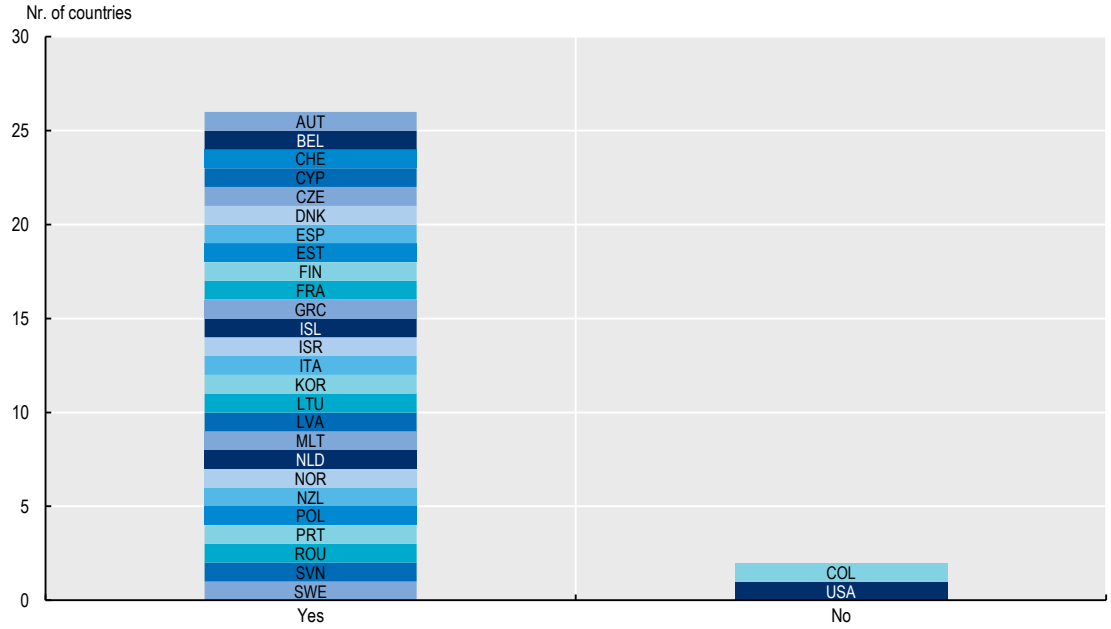
Question B9: Can a regulated price be modified once it has been determined?



Source: OECD survey on Price Transparency/On-patent competition 2022.

Figure A C.11. Denial of coverage for products whose prices are considered excessive

Question B10: Can coverage be denied for products whose prices are considered excessive? Please, select one the options



Source: OECD survey on Price Transparency/On-patent competition 2022.

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