

Drug Money Part 3: How do International Drug-Pricing Policies compare to U.S. Policies?

Introduction

As discussed in earlier Drug Money Issue Briefs, spending on pharmaceuticals is a large and growing concern in the United States and the world. In 2013, the countries in the Organization for Economic Co-operation and Development (OECD) spent \$800 billion, accounting for nearly 20% of all health expenditures.[\[1\]](#) Even among OECD countries, however, the U.S. stands out for large spending on pharmaceuticals. In 2014, the U.S. spent \$1,112 per capita on pharmaceuticals – more than double the average spending for the countries in the OECD and ~40% more than Canada, the country that spent the next highest amount.[\[2\]](#) Many OECD-member countries spend much less per capita on pharmaceuticals|Norway spends \$460, Portugal spends \$400, and Denmark spends only \$325 per capita.[\[3\]](#)

In an idealized free market, different firms compete until marginal costs and benefits align. The forces of supply and demand determine the price of the produced goods|no independent organization needs to set the value of the goods. As discussed in [Drug Money \(Part 1\): What Limits Competition in the Pharmaceutical Market?](#), however, the pharmaceutical market does not behave like an optimal free market, and pharmaceutical prices often do not reflect the benefits received by patients. As a result of the inefficient market for pharmaceuticals, all OECD countries, except the U.S., consider costs when determining whether the national health system should cover drug reimbursement.

Since the mid-2000s, the prices of existing drugs have been stable or even declining in many OECD countries due to regulation changes and generic competition.[\[4\]](#) In addition, since 2005, pharmaceutical prices have increased more slowly than other health expenditures in most OECD countries.[\[5\]](#) In the U.S., the Center for Medicare and Medicaid Services (CMS) reported that growth in spending for prescriptions was at or below other components of healthcare spending for 2010 through 2015.[\[6\]](#) That trend may be changing, however. Currently, one-third of pharmaceutical spending in the U.S. is for expensive specialty and biologic drugs, and that fraction is rising.[\[7\]](#) The OECD predicts that increased use of these specialty drugs may represent half of future spending growth for pharmaceuticals in North America (and nearly *all* of the spending growth in many European countries) between 2013 and 2018.[\[8\]](#) If these predictions are accurate, it is imperative for countries to consider policy options that keep prices low enough so that patients can access necessary medications and countries can contain overall pharmaceutical expenditures.

Current International Policies that Ensure Pharmaceutical Prices Reflect Clinical Benefit

External price referencing (EPR) is the most commonly used policy among OECD countries|30 of the 32 European countries use EPR in at least some of their drug pricing.[\[9\]](#) When using EPR, a country uses the price(s) of a medicine in one or more countries in order to derive a benchmark or reference price to set the price of the product that country. The wide-spread use of EPR, however, creates an incentive for manufacturers limit or delay access to new treatments in countries with small markets and/or lower prices.[\[10\]](#) Ideally, policies for pricing drugs should create a system that mimics a free-market so that costs for drugs reflect their benefit to patients. Most OECD countries, including Australia, Belgium, France, Italy, Canada's public plans, Korea, the Netherlands, Norway,

and Sweden, consider cost-effectiveness[\[11\]](#) as part of the drug approval process.[\[12\]](#)

Historically, the United Kingdom (UK) avoided direct controls on prices, but rather relied on the Pharmaceutical Price Regulation Scheme (PPRS), which is a voluntary agreement between the Department of Health and drug manufacturers that aims “to increase[e] patient access to medicines and ensur[e] prices of medicines better reflect their value.”[\[13\]](#) Additionally, the National Institute of Health and Care Excellence (NICE) sets a cost-utility threshold of £20,000-£30,000 per quality-adjusted life-year (QALY) for a drug covered by the National Health Service (NHS).[\[14\]](#) In some circumstances, NICE has approved coverage for drugs with a higher price per QALY.[\[15\]](#)

In response to price hikes to some medications and an escalating cost of drugs covered by the NHS, the UK passed the Health Service Medical Supplies (Costs) Bill in April 2017. The bill gives additional oversight powers to the PPRS and grants the UK government the power “to reduce the price of unbranded generic medicines if the competitive market is not appropriately functioning in the case of a small number of specific products,”[\[16\]](#) and requires sales, profits, and other information from manufacturers, distributors, and suppliers in the pharmaceutical supply chain.[\[17\]](#) The UK relied on competition to keep prices low for unbranded generic medications and, in markets where there was only one manufacturer, the UK (like the US) faced large increases in prices. The UK passed this law to allow the government to set prices where lack of competition has resulted in drug prices that are “unreasonably high.”[\[18\]](#)

Policies in the UK try to balance innovation with cost-effectiveness and patient access. The government does not set prices for pharmaceuticals, but rather has established policies to ensure patients and the NHS are receiving appropriate value for the money they spend on

pharmaceuticals. The recent legislation demonstrates the willingness of the UK government to set prices when the market fails to provide an appropriate level of competition to ensure that drugs remain cost-effective.

Until recently, German policies, like those in the UK, primarily allowed market forces to set drug prices. In response to increasing drug expenditures, however, Germany has also implemented new policies to ensure that new medications have prices commensurate with their value. Before 2011, Germany allowed pharmaceutical companies to set their own prices, resulting in prices that were 26% higher in Germany than the rest of Europe.[\[19\]](#) The Act for Restructuring the Pharmaceutical Market in Statutory Health Insurance (*Arzneimittelmarktneuordnungsgesetz*, AMNOG) instituted a process by which companies set the price when the drug enters the market. During the first six months of use, however, the company must submit data to the German public health agency, the *Gemeinsamer Bundesausschuss* (G-BA) to assess the effectiveness of the new drug relative to those already on the market.[\[20\]](#) If the drug does not demonstrate improved efficacy, health insurance funds will reimburse for the new drug according to the cheapest comparable treatment. This comparison is particularly important if there is a generic drug on the market because the reimbursement for the newly released branded drug will be set at the same rate as the generic drug unless the branded drug demonstrates improved efficacy. If the drug demonstrates added efficacy, the pharmaceutical company and the Federal Association of Statutory Health Insurance Funds (*GKV-Spitzenverband*, GKV-SV) will negotiate an appropriate price that reflects the degree of the pharmaceutical's additional benefit and prices in other European countries.[\[21\]](#)

In the first four years of AMNOG, GKV-SV negotiated prices for 193 drugs, finding that 100 offered additional benefit over existing therapies.[\[22\]](#) The health insurance funds saved 180

million euros, or \$247 million, for the first 29 drugs subject to price negotiation.[\[23\]](#) The bulk of the savings, however, likely comes from the drugs that do not demonstrate improved efficacy and are, therefore, subject to reference pricing. Critics of AMNOG call it unnecessarily complex because it does not clearly link prices to efficacy.[\[24\]](#) In the first four years of AMNOG, manufacturers withdrew 13 branded drugs from the German market after their prices were set to a comparable generic treatment.[\[25\]](#) Nevertheless, in 2015 alone, Germany achieved savings of \$1 billion on new drug spending.[\[26\]](#) Between 2009 and 2013, the average annual growth rate in public drug expenditure per capita in Germany was -0.7%, as compared with +2.7% in the US.[\[27\]](#)

Does the Government Help Establish Drug Prices in the U.S.?

In the United States, unlike all other OECD countries, no governmental agency has the statutory authority to consider prices or relative benefit provided by a drug during the approval process. The FDA does not consider price when it decides whether to approve a drug.[\[28\]](#) The U.S. even prevents the Centers for Medicare and Medicaid Services (CMS) from negotiating prices of drugs for its Medicare beneficiaries.[\[29\]](#) The Affordable Care Act created the Patient-Centered Outcomes Research Institute (PCORI) to examine the “relative health outcomes, clinical effectiveness, and appropriateness” of different medical treatments by evaluating existing studies and conducting its own,[\[30\]](#) but Congress expressly prohibited PCORI from developing or employing “dollars-per-quality adjusted life year [QALY]... as a threshold to establish what type of health care is cost effective or recommended.”[\[31\]](#) The ban on using cost-per-QALY thresholds seems to reflect long-standing concerns that the approach would discriminate on the basis of age and disability and a fear that PCORI could be used to ration healthcare to vulnerable populations.[\[32\]](#) QALY’s critics argue that the

metric unfairly favors younger and healthier populations that have more potential QALYs to gain.”[\[33\]](#) The restrictions on PCORI’s use of cost-effectiveness measures may be more semantics than actual prohibitions, however, as PCORI can still consider the relative costs and even QALYs although it cannot use them to establish a cost-effectiveness threshold. Nevertheless, the language in the statute and the legislative history of the restrictions on PCORI reflect a hesitancy on the part of the government to consider costs when determining the effectiveness and appropriateness of treatments.

In response to the government’s reluctance to consider cost-effectiveness, independent groups have begun issuing value-based guidance on pharmaceutical pricing. Two groups, the Institute for Clinical and Economic Review (ICER) and DrugAbacus, analyze evidence about the improvements in patient outcomes from pharmaceuticals and convert them into a price that is based on the value to the patient.[\[34\]](#) In addition, many professional societies, including the National Comprehensive Cancer Network,[\[35\]](#) the American Heart Association and the American College of Cardiology,[\[36\]](#) compare the benefits and prices for treatments in their specialties, yet these organizations have no formal ability to control drug expenditures. Instead of legal requirements that drug prices reflect the recommendations of these independent groups, the U.S. relies on market forces to ensure that prices reflect value.

Conclusion

If the pharmaceutical market operated as an ideal market, relying on competition and market pressures to contain costs would likely be sufficient to ensure that the price of a drug was commensurate with its clinical value. The first issue brief in this series, [Drug Money \(Part 1\): What Limits Competition in the Pharmaceutical Market?](#), discusses

limitations to the pharmaceutical market that prevent it from operating as a free market. In order to ensure that drug expenditures remain consistent with value to patients, the U.S. should consider adopting policies like those in the UK and Germany that allow the government to step in when the market fails to incorporate cost-effectiveness considerations into pricing. Encouraging innovative new treatments should be balanced against ensuring that patients have access to treatment and ensuring that the health system is receiving appropriate value for the money spent on pharmaceuticals.

[1] Belloni, A., D. Morgan and V. Paris (2016), "Pharmaceutical Expenditure And Policies: Past Trends And Future Challenges", OECD Health Working Papers, No. 87, OECD Publishing, Paris. <http://dx.doi.org/10.1787/5jm0q1f4cdq7-en>.

[2] OECD (2017), Pharmaceutical spending (indicator). doi: 10.1787/998feb6-en (Accessed on 08 September 2017). Available at <https://data.oecd.org/healthres/pharmaceutical-spending.htm>. This data excludes pharmaceuticals dispensed in a hospital.

[3] OECD/EU (2016), Health at a Glance: Europe 2016 – State of Health in the EU Cycle, OECD Publishing, Paris. <http://dx.doi.org/10.1787/9789264265592-en>.

[4] Belloni, A., D. Morgan and V. Paris (2016), "Pharmaceutical Expenditure and Policies: Past Trends and Future Challenges", OECD Health Working Papers, No. 87, OECD Publishing, Paris. <http://dx.doi.org/10.1787/5jm0q1f4cdq7-en>.

[5] Belloni *supra* p. 18.

[6] Quintiles IMS Institute "Understanding the Drivers of Drug Expenditures in the U.S." Available at: http://www.imshealth.com/files/web/IMSH%20Institute/Reports/QI_IHI_Understanding_the_Drivers_of_Drug_Expenditure_US.pdf.

[7] Quintiles IMS Institute

[8] Belloni *supra* p. 34.

[9] European Commission. *Study on enhanced cross-country coordination in the area of pharmaceutical product pricing. Final Report. December 2015.* Available at: https://ec.europa.eu/health/sites/health/files/systems_performance_assessment/docs/pharmaproductpricing_frep_en.pdf. See section 4.1.1.2 for a detailed description of how individual countries use EPR in their assessments.

[10] Persson, Ulf, and Bengt Jönsson. "The End of the International Reference Pricing System?". *Applied Health Economics and Health Policy* 14, no. 1 (February 01 2016): 1-8|Remuzat, C., D. Urbinati, O. Mzoughi, E. El Hammi, W. Belgaied, and M. Toumi. "Overview of External Reference Pricing Systems in Europe." *J Mark Access Health Policy* 3 (2015)|Espin J, Rovira J, de Labry A0. Working paper 1: External Price Referencing – review series on pharmaceutical pricing policies and interventions. Geneva: World Health Organization and Health Action International, 2011.

[11] The term "cost-effectiveness" is used here to refer to any consideration of both costs and effectiveness. It encompasses cost-effectiveness analysis (CEA), cost-benefit analysis (CBA), cost-utility analysis (CUA), cost-consequence analysis (CCA), and cost-minimization analysis (CMA).

[12] Paris, V. and A. Belloni (2013), "Value in Pharmaceutical Pricing", OECD Health Working Papers, No. 63, OECD Publishing, Paris. <http://dx.doi.org/10.1787/5k43jc9v6knx-en>.

[13] Pharmaceutical Price Regulation Scheme (PPRS). Available at: <https://www.gov.uk/government/publications/pharmaceutical-price-regulation-scheme>.

[14] Chalkidou K. Comparative Effectiveness Review Within the

U.K.'s National Institute for Health and Clinical Excellence.
July
2009|http://www.commonwealthfund.org/~media/Files/Publications/IssueBrief/2009/Jul/Chalkidou/1296_Chalkidou_UK_CER_issue_brief_717.pdfPublished. Accessed December 18, 2016.

[15] Paris *supra* p. 49.

[16] "ABPI Analysis: Health Service Medical Supplies (Costs) Bill." The Pharma Letter. May 2017.
<https://www.thepharmaletter.com/article/abpi-analysis-health-service-medical-supplies-costs-bill>. Accessed September 14, 2017.

[17] Tillett, Charlotte and Astrid Arnold. "New UK law to Control Generic Drug Prices – Implications for Pharma." PharmaPhorum. June 7, 2017.
<https://pharmaphorum.com/views-and-analysis/uk-drug-pricing-legislation/>.

[18] Guidance: Health Service Medical Supplies (Costs) Bill factsheet. Department of Health, United Kingdom. Updated Nov. 8, 2016. Available at:
<https://www.gov.uk/government/publications/health-service-medical-supplies-costs/health-service-medical-supplies-costs-bill-factsheet>.

[19] Sieler Sebastian, Thomas Rudolph, Carola Brinkmann-Sass, Richard Sear. "AMNOG Revisited: How has German health reform impacted pharma pricing and market access, and what can the industry learn from the experience?" *McKinsey and Co.* originally published in PharmaTimes May 2015. Accessed here:
<http://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/amnog-revisited>.

[20] Henschke, Cornelia, Leonie Sundmacher, and Reinhard Busse. "Structural Changes in the German Pharmaceutical Market: Price Setting Mechanisms Based on the Early Benefit

Evaluation." *Health Policy* 109, no. 3: 263-69.

[21] Ibid. If negotiations fail during the first year after launch, an arbitration body – consisting of representatives of the GKV-SV, the pharmaceutical industry, and neutral members – sets the price within the following three months.

[22] *Ibid.*

[23] Bahr, Daniel and Thomas Huelskoetter "Comparing the Effectiveness of Prescription Drugs: The German Experience" *Center for American Progress*. Published May 21, 2014. Accessed here:

<https://www.americanprogress.org/issues/healthcare/reports/2014/05/21/90120/comparing-the-effectiveness-of-prescription-drugs-the-german-experience/>.

[24] *Ibid.*

[25] Sieler, *supra* note 14.

[26] Lauterbach K, McDonough J., and Seeley E. Germany's Model for Drug Price Regulation Could Work In The US. *Health Affairs Blog*. December 29, 2016. <http://healthaffairs.org/blog/2016/12/29/germanys-model-for-drug-price-regulation-could-work-in-the-us/>.

[27] *Ibid.*

[28] FDA's Drug Review Process: Continued. *U.S. Food and Drug Administration*. Updated August 24, 2015. <https://www.fda.gov/drugs/resourcesforyou/consumers/ucm289601.htm>.

[29] Social Security Act § 1860D-11(i) (2017).

[30] PCORI Mission Statement found here: <http://www.pcori.org/about-us>.

[31] 42 U.S.C. § 1320e-1 Limitations on certain uses of

comparative clinical effectiveness research (2017).

[32] Glick HA, S. McElligott, M. V. Pauly, R. J. Willke, H. Bergquist, J. Doshi, L. A. Fleisher, et al. "Comparative effectiveness and cost-effectiveness analyses frequently agree on value." *Health Affairs*. 34, no. 5 (May 2015):805-811|Sen. Mike Enzi (R-WY) joined other Republicans in comparing PCORI to NICE in the U.K., using the comparison to raise fears of rationing and "death panels" (Patel K. "Health reform's tortuous route to the patient-centered outcomes research institute." *Health Affairs*.29, no. 10 (October 2010):1777-1782).

[33] Neumann, P. J., and M. C. Weinstein. "Legislating against Use of Cost-Effectiveness Information." *N Engl J Med* 363, no. 16 (Oct 14 2010): 1495-7.

[34] Bach, P. B., and S. D. Pearson. "Payer and Policy Maker Steps to Support Value-Based Pricing for Drugs." *JAMA* 314, no. 23 (2015): 2503-04.

[35] Nardi, E. A., J. A. Wolfson, S. T. Rosen, R. B. Diasio, S. L. Gerson, B. A. Parker, J. C. Alvarnas, et al. "Value, Access, and Cost of Cancer Care Delivery at Academic Cancer Centers." *J Natl Compr Canc Netw: JNCCN* 14, no. 7 (Jul 2016): 837-47.

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[36] Anderson, J. L., P. A. Heidenreich, P. G. Barnett, M. A. Creager, G. C. Fonarow, R. J. Gibbons, J. L. Halperin, et al. "ACC/AHA Statement on Cost/Value Methodology in Clinical Practice Guidelines and Performance Measures: A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and Task Force on Practice Guidelines." *Circulation* 129, no. 22 (Jun 03 2014): 2329-45.