



# **Examination of International Drug Pricing Policies in Selected Countries Shows Prevalent Government Control over Pricing and Restrictions on Access**

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# Examination of International Drug Pricing Policies in Selected Countries Shows Prevalent Government Control over Pricing and Restrictions on Access

By Doug Badger<sup>1</sup>

## Abstract

The Trump Administration has proposed using its demonstration authority under section 1115A of the Social Security Act to test a method of reimbursement for physician-administered drugs based on prices in 14 countries. The proposal is controversial, raising constitutional questions about the agency's authority to modify Medicare reimbursement absent congressional action, as well as objections to the use of international reference pricing. A recent paper from the Foundation for Research on Equal Opportunity (FREOPP) makes a useful contribution to this debate. The FREOPP paper recommends that the administration construct a market-based international index (MBII) that would exclude "industrialized countries with little room for market-based pricing." This report examines the drug pricing and reimbursement policies in MBII countries and finds that these policies are generally not market-based. Secondly, it presents data showing that many drugs introduced between 2011 and 2018 are not available to consumers in MBII countries. Under the proposal advanced by the administration and that suggested by FREOPP, Medicare reimbursement for physician-administered drugs would largely be based on international reference prices in which the regulatory agency of one government sets drug prices based at least in part on those set by regulatory agencies in other countries. Importing these mutually reinforcing, centralized decisions into Medicare may reduce reimbursement for physician-administered drugs, but the new reimbursement system cannot be said to be based on market prices.

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## Introduction and Background

Medicare has two separate reimbursement systems for prescription drugs. Part D generally covers medicines that beneficiaries obtain from brick-and-mortar and mail-order pharmacies.<sup>2</sup> Part B covers drugs furnished incident to a physician's services that are not ordinarily self-administered by patients.<sup>3</sup> Part D is largely a market-based program, in which competing pharmacy benefit managers negotiate price concessions and rebates with manufacturers in exchange for market share.<sup>4</sup>

The administration has published an advance notice of proposed rulemaking (ANPRM), announcing its intention to test a new method of reimbursing for physician-administered drugs under Medicare Part B.<sup>5</sup> The ANPRM cites section 1115A of the Social Security Act as providing the Secretary of Health and Human Services with the authority to undertake the demonstration project. This section describes how the reimbursement system established by statute works and examines the demonstration authority that the Secretary of Health and Human Services plans to use to test an alternative system.

### *Physician-administered drugs*

Part B reimburses for physician-administered drugs based on the amount manufacturers charge for their products. Typically, hospital outpatient departments and medical practices (e.g., oncology practices that administer chemotherapy) obtain drugs from distributors, store them and administer them at the facility. They bill Medicare both for the cost of the drug itself and the cost of administering it to patients.

The statute requires the HHS Secretary to reimburse for most physician-administered drugs at six percentage points above their "average sales price" (ASP+6).<sup>6</sup> The agency computes the ASP based on quarterly reports from manufacturers on the volume-weighted sales price for each of their products, net

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<sup>2</sup> 42 U.S.C. 1395w et seq.

<sup>3</sup> 42 U.S.C. 1395x(s)(2)(A).

<sup>4</sup> Over the years, Congress has injected government price controls into the Part D program.

The government, for example, requires manufacturers to provide a 70 percent discount on their products when purchased by a beneficiary in the program's "coverage gap" (42 USC 1395w-114a(g)(4)(A)).

<sup>5</sup> 83 *Federal Register* 54546, October 30, 2018. <https://www.govinfo.gov/content/pkg/FR-2018-10-30/pdf/2018-23688.pdf>

<sup>6</sup> 42 U.S.C. 1395w-3a(b)(1).



of discounts, rebates and other price concessions.<sup>7</sup> Multisource drugs are reimbursed under the same billing code, which represents the weighted sales price for both brand name drugs and generics.<sup>8</sup> Single source drugs are reimbursed at the lesser of ASP+6 or six percentage points above wholesale acquisition cost (WAC+6).<sup>9</sup> Effective January 1, 2019, new drugs for which an ASP is unavailable are reimbursed at WAC+3 percent and then moved to an ASP+6 once a full quarter of data on sales prices becomes available.<sup>10</sup>

Sequestration has reduced add-on payments from six percentage points to 4.3 percentage points for drugs on the ASP+6 and WAC+6 payment schedule and to 1.35 percentage points for drugs on the WAC+3 schedule.<sup>11</sup> These add-on payments are intended to address provider costs associated with handling and storage of covered drugs, as well as distributor markup. It also is meant to compensate for the fact that, by definition, some providers will pay a sales price that exceeds the average.

Critics of the Part B reimbursement methodology have faulted both the add-on payments and the calculation of ASP. They note that, since the add-on payments rise with ASP, providers have an incentive to administer more costly drugs to their patients. They also note that Medicare Part B drug spending is rising rapidly. Implementation of the ASP system in 2005 resulted in an eight percent reduction in Part B drug spending, followed by several years in which increases averaged four percent.<sup>12</sup>

But as with most Medicare reimbursement systems, this period of moderate growth did not last. Spending increased from \$17.6 billion in 2011 to \$28.0 billion in 2016, an average annual increase of 9.8 percent.<sup>13</sup> While some of this is due to a rise in the number of beneficiaries, CMS believes that the spending increase “is more fully explained by increases in the prices of drugs and mix of drugs for those beneficiaries ... than by increase in Medicare enrollment and drug utilization.”<sup>14</sup>

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<sup>7</sup> 42 U.S.C. 1395w-3a(c).

<sup>8</sup> “Part B Drugs Payment Systems,” Medicare Payment Advisory Commission (MedPAC), p. 3. [http://www.medpac.gov/docs/default-source/payment-basics/medpac\\_payment\\_basics\\_17\\_partb\\_final.pdf?sfvrsn=0](http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_17_partb_final.pdf?sfvrsn=0)

<sup>9</sup> 42 U.S.C. 1395w-3a(b)(1)&(4).

<sup>10</sup> 83 *Federal Register* 59452, November 23, 2018. <https://www.govinfo.gov/content/pkg/FR-2018-11-23/pdf/2018-24170.pdf> The regulation was issued pursuant to 42 U.S.C. 1395w-3a(c)(4), which authorizes the Secretary to establish a payment methodology for drugs for which one quarter of sales data is unavailable. Since there is a two-month lag in reporting quarterly sales price data, this means that a new drug is generally reimbursed under the WAC-based methodology for three quarters.

<sup>11</sup> Marti Ross and Lori Foley, “Effective January 1, 2019 – Changes to Part B Drug Pricing,” PYA Insights, November 16, 2018. <https://www.pyapc.com/insights/effective-january-1-2019-changes-to-part-b-drug-pricing/>

<sup>12</sup> Angela Boothe, “Primer: Part B Drug Payment System,” American Action Forum, January 1, 2015. <https://www.americanactionforum.org/research/primer-medicare-part-b-drug-payment-system/>

<sup>13</sup> 83 FR 54549.

<sup>14</sup> *Ibid.*





### ***Center for Medicare and Medicaid Innovation (CMMI)***

The Affordable Care Act created CMMI and vested it with extraordinary powers.<sup>15</sup> In conducting a CMMI demonstration project, section 1115A of the Social Security Act empowers the Secretary to waive a broad range of statutory provisions.<sup>16</sup> The agency can compel beneficiaries and providers to participate in the demonstration. CMMI demonstration projects need not be budget neutral in their initial phase.<sup>17</sup> The statute also shields CMMI projects against administrative and judicial review.<sup>18</sup>

Such projects have two phases. During Phase I, the Secretary can test a broad range of models. The Secretary is required to conduct an evaluation of the demonstration project to determine whether it improved health care quality without increasing costs or reduced costs without adversely affecting quality.<sup>19</sup>

If the Secretary, in consultation with the Actuary for the Center for Medicare and Medicaid Services (CMS), determines a project to have met these criteria, it can move to Phase II. During this phase, the Secretary:

*may, through rulemaking, expand (including implementation on a nationwide basis) the duration and the scope of a model that is being tested, ... to the extent determined appropriate by the Secretary.*<sup>20</sup>

Acting through CMMI, the Secretary thus is authorized to do through rulemaking what constitutionally requires an Act of Congress: make a change in the Medicare program that is permanent in duration and nationwide in scope.

This is an unprecedented grant of power to the HHS Secretary. The Secretary has long-standing statutory authority to test innovations in the Medicare program.<sup>21</sup> Such tests must be limited in duration and scope and subject to evaluation.<sup>22</sup>

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<sup>15</sup> 42 USC 1315a, codifying section 1115A of the Social Security Act.

<sup>16</sup> 42 USC 1315a(d)(1).

<sup>17</sup> 42 USC 1315a(b)(3).

<sup>18</sup> 42 USC 1315a(d)(2).

<sup>19</sup> 42 USC 1315a(c)(1)&(2).

<sup>20</sup> 42 USC 1315a(c).

<sup>21</sup> 42 USC 1395b-1.

<sup>22</sup> It can be argued that by creating two phases of demonstration programs (a test phase and an expansion phase), the statutory language also intends that Phase I CMMI demonstrations be limited in scope. As discussed below, the ANPRM envisions applying a new reimbursement formula to 50 percent of all Medicare Part B prescription drug spending. A demonstration of that size may be inconsistent with the statutory language authorizing Phase I CMMI demonstrations.



Extending the scope and duration of these tests has long been understood to be a prerogative of Congress, which has enacted and revised Medicare reimbursement regimes for myriad medical goods and services, including for physician-administered drugs.<sup>23</sup>

As will be discussed in the following section, two HHS secretaries have claimed authority under CMMI to mandate a Medicare Part B payment mechanism without having to seek new legislation. Use of this authority would establish a chasm between the statute and agency practice. The Social Security Act would continue to require the Secretary to reimburse for physician-administered drugs at ASP+6, even as the Secretary expended tens of billions of federal dollars in accordance with a reimbursement methodology of his or her own devising. The Secretary, by promulgating a regulation, would render the statute a dead letter.

The Secretary's power under CMMI is constitutionally suspect. Congress wrote the Social Security Act under legislative authority granted under Title I of the Constitution. Congress cannot constitutionally confer on the executive branch the ability to establish and employ a parallel reimbursement system unhinged from the statute. Nor can it outsource authority to effectively rewrite portions of that statute to the HHS Secretary.

These constitutional infirmities make litigation inevitable should the Secretary exercise the powers Congress has granted.<sup>24</sup> Such litigation will create a climate of uncertainty for patients and providers.

## Medicare Part B Drug Reimbursement Demonstrations Under CMMI

### *Obama administration proposal*

In March 2016, CMMI sought comment on a proposed five-year demonstration project to test new ways of reimbursing for physician-administered drugs under Medicare.<sup>25</sup>

The Obama administration did not suggest altering the calculation of ASP, but instead focused on add-on payments. During Phase I, the country would be split between a control group, which would be reimbursed at the statutory rate of ASP+6, and an experimental group, reimbursed at ASP+2.5, plus a flat fee of \$16.80. During Phase II, each of those two

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<sup>23</sup> MedPAC has published no fewer than 20 papers describing various Medicare payment methodologies in its "Payments Basics" series. <http://medpac.gov/-documents-/payment-basics>

<sup>24</sup> 42 USC 1315a(d)(2)(F) proscribes judicial review of the "expansion of the duration and scope of a model." It is unlikely that this provision would deter federal judges from scrutinizing the constitutionality of a Secretary's decision to make a demonstration nationwide and permanent.

<sup>25</sup> "CMS Proposes to Test New Medicare Part B Prescription Drug Models to Improve Quality of Care and Deliver Better Value for Medicare Beneficiaries," CMS Fact Sheet, March 8, 2016. <https://www.cms.gov/newsroom/press-releases/cms-proposes-test-new-medicare-part-b-prescription-drug-models-improve-quality-care-and-deliver>



groups would be subdivided. The control group would be split between those reimbursed at ASP+6 and those that would operate under the same payment formula but also would have authority to apply “value-based purchasing tools” (e.g. varying reimbursement based on a drug’s clinical effectiveness for different indications, entering into risk-sharing arrangements with manufacturers).<sup>26</sup> The experimental group also would be subdivided, with half being subject to value-based purchasing tools.

The proposal drew widespread criticism.<sup>27</sup> The Obama administration announced in December 2016 that it would not publish a final rule that would have launched the project.<sup>28</sup> In October 2017, the Trump administration formally withdrew the proposal.<sup>29</sup>

### ***Trump administration proposal: International Price Index***

That did not end HHS efforts to use its expansive powers under CMMI to reshape Medicare reimbursement for physician-administered drugs. A year later, the Trump administration issued an advance notice of proposed rulemaking (ANPRM) announcing its intention to propose a far more sweeping Medicare Part B drug demonstration project.<sup>30</sup>

That proposal would change both the arrangements that doctors and hospital outpatient departments have made to procure and bill Medicare for physician-administered drugs and scrap the ASP Medicare reimbursement methodology in favor of one based on drug prices paid in other countries.

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<sup>26</sup> “CMS Proposes To Test New Medicare Part B Prescription Drug Model To Improve Quality of Care and Deliver Better Value for Medicare Beneficiaries,” Centers for Medicare and Medicaid Services, March 8, 2016. <https://www.cms.gov/newsroom/press-releases/cms-proposes-test-new-medicare-part-b-prescription-drug-models-improve-quality-care-and-deliver>

<sup>27</sup> See, for example, “Center for Medicare and Medicaid Innovation: Scoring Assumptions and Real-World Implications,” House Budget Committee, September 7, 2016. <https://budget.house.gov/legislation/hearings/center-medicare-and-medicare-innovation-scoring-assumptions-and-real-world>

<sup>28</sup> Rachel Dolan, “The Demise of the Part B Demo: Doom for Value-Based Payment?” Health Affairs Blog, December 27, 2016. <https://www.healthaffairs.org/doi/10.1377/hblog20161227.058082/full/>

<sup>29</sup> “Medicare Program: Part B Drug Payment Model; Withdrawal,” 82 Federal Register, 46182, October 4, 2017. <https://www.govinfo.gov/content/pkg/FR-2017-10-04/pdf/2017-21420.pdf>

<sup>30</sup> 83 Federal Register 54546, October 30, 2018. <https://www.govinfo.gov/content/pkg/FR-2018-10-30/pdf/2018-23688.pdf>



The new system has three major features<sup>31</sup>:

- 1. Medicare reimbursement.** The reimbursement amount for selected Part B drugs would be phased down to align more closely with prices for those drugs in selected countries.
- 2. Third-party vendors.** CMS would contract with vendors, who would negotiate with manufacturers over wholesale prices for drugs, take title to the drugs and supply them to physicians and hospitals. The agency would reimburse these vendors based in part on drug prices paid in foreign countries.
- 3. Add-on payments.** The agency would pay doctors and hospitals the add-on based on a “set payment amount” structure. CMS would calculate the amount it would have paid under the ASP system absent sequestration “and redistribute this amount to model participants based on a set payment amount.”

The agency’s proposal to base Medicare reimbursement for physician-administered drugs on foreign prices has attracted the most attention—both favorable and unfavorable—and this paper will examine that feature of the proposal.

CMS is considering the establishment of an “international price index” (IPI). It would calculate the IPI based on the average price per standard unit of a drug in select foreign countries.<sup>32</sup> It would then determine how much the Medicare reimbursement for each included Part B drug would have to be reduced in order to achieve “about a 30 percent reduction in Medicare spending for included Part B drugs over time.”<sup>33</sup> The resulting “target price” would then be phased in over a five-year period. CMS estimates that the program would produce Medicare savings of \$16.3 billion between fiscal years 2020 and 2025.<sup>34</sup>

Even in its initial phase, the demonstration would cover a broad enough geographic area to account for “50 percent of Medicare spending on separately payable Part B drugs.”<sup>35</sup> The agency would compel doctors and hospital outpatient departments and patients in these areas to participate in the demonstration.<sup>36</sup>

The agency is considering using drug prices in the following countries in its IPI: Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, the Netherlands and the United Kingdom.<sup>37</sup> This list overlaps considerably with those included in an October 2018 HHS study of international drug prices (see Appendix 2,

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<sup>31</sup> 83 FR 54547.

<sup>32</sup> Ibid, p. 54556.

<sup>33</sup> Ibid.

<sup>34</sup> Ibid, p. 54560.

<sup>35</sup> Ibid.

<sup>36</sup> Ibid, p. 54533.

<sup>37</sup> Ibid, p. 54557.





which lists both HHS and IPI countries).

The agency’s rationale for including this list of countries is unclear. The ANPRM describes them as “either economies comparable to the United States or ... included in Germany’s market basket for reference pricing for their drug prices, and existing data sources contain pricing information for those prices.”<sup>38</sup>

This seems a rather fuzzy and confused set of criteria. It is unclear, for example, what led CMS to conclude that the Greek and Czech economies are “comparable to the United States.” But even the other countries on the proposed list have lower living standards than do Americans, as measured by per capita household disposable income, as Table 1 illustrates.

**Table 1. Gross Adjusted Household Disposable Income Per Capita in 2017**

Country	Disposable Income (USD)	Percentage of U.S.
United States	\$47,842	100
Germany	\$36,871	77
Austria	\$35,282	74
Canada	\$32,944	69
France	\$32,845	69
Belgium	\$32,364	68
Denmark	\$31,972	67
Finland	\$31,810	66
Netherlands	\$31,633	66
Japan	\$31,539	66
United Kingdom	\$30,369	63
Italy	\$29,044	61
Ireland	\$25,995	54
Czech Republic	\$22,495	47
Greece	\$19,174	40

Source: Statista.com <https://www.statista.com/statistics/725764/oecd-household-disposable-income-per-capita/>

The median disposable per-capita income in the IPI countries is thus about one-third less than in the U.S. Although per capita GDP is often used as a proxy for living standards, per-capita disposable income is a more accurate measure, since it captures the consumption capacity of households. In addition to measuring economic well-being, per capita disposable income better predicts how much a country spends on health care than does per capita GDP. And while there is a distinction between spending and prices, there is empirical evidence that a

<sup>38</sup> Ibid.



country's relative affluence is well correlated with its medical spending.<sup>39</sup>

CMS thus overlooks salient economic differences between the U.S. and IPI countries, making its assertion that their economies are “comparable” to that of the U.S. questionable.

The agency's use of Germany's market basket of reference prices as a criterion for inclusion also is puzzling. Virtually all European countries use international reference pricing, creating a web of mutually-reinforcing government-established drug prices. It's not clear what makes Germany unique. Nor is it clear why CMS included Greece (which Germany has temporarily excluded from its reference pricing) or excluded Portugal, Sweden, Slovakia and Spain, all of which are included in Germany's drug reference pricing.<sup>40</sup>

The agency's third criterion—availability of data—also appears arbitrary. HHS attaches a good deal of weight to pricing information compiled by IQVIA, a health care consultancy whose dataset formed the basis of its aforementioned October 2018 report on foreign drug prices.<sup>41</sup> But the ANPRM also states that CMS is “contemplating a data collection system for manufacturers to report to CMS their international drug sales data to support the calculation of the IPI and the Target Price for each drug.”<sup>42</sup> Since the agency believes it can compel manufacturers (including those domiciled outside the United States) to report their overseas prices, it is not clear why the availability of drug price data from IQVIA or other private sources should influence the agency's decision about which countries to include in its reference pricing regime.

In short, the ANPRM offers no coherent methodology for determining which countries to include in its international pricing index. The list of proposed IPI countries appears arbitrary.

## Market Based International Index

In a recent paper published by the Foundation for Research on Equal Opportunity (FREOPP), Avik Roy has proposed what he terms a “Market-Based International Index” (MBII).<sup>43</sup> The FREOPP paper makes an important contribution to the discussion about the

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<sup>39</sup> See, for example, Peter Laakmann, “Unique Features of the U.S. Health Care System Are Unlikely To Be A Major Cause of High U.S. Health Spending.” <https://empiricalscrutiny.com/2017/09/26/unique-features-of-the-us-health-care-system-are-unlikely-to-be-a-major-cause-of-high-us-health-spending-abbreviated-version/> See also Laakmann, “The Price is Right,” *National Review*, October 16, 2017. <https://www.nationalreview.com/magazine/2017/10/16/price-right/>

<sup>40</sup> *Pharmaceutical Reimbursement and Pricing in Germany*, OECD, June 2018, p. 12, FN 3. <http://www.oecd.org/els/health-systems/Pharmaceutical-Reimbursement-and-Pricing-in-Germany.pdf>

<sup>41</sup> The ANPRM calls this data source “appropriate” and states that it “could be used for the purposes of the potential IPI model” (83 FR 54556).

<sup>42</sup> 83 FR 54556. This is, of course, the system it currently uses to establish ASP, although reporting sales data from multiple countries and converting them to U.S. prices in any economically comparable way would be infinitely more complicated.

<sup>43</sup> Avik Roy, “What Medicare Can Learn from Other Countries on Drug Pricing,” *Foundation for Research on*



proposed IPI demonstration project. In particular, it offers a coherent criterion for selecting countries for a reference pricing basket:

“In this paper, we propose an alternative benchmark: the Market-Based International Index. The MBII excludes industrialized countries with little room for market-based pricing, due to an absence of private insurance and the presence of regulated drug prices.”<sup>44</sup>

The MBII divides the countries it proposes to use for reference pricing into two tiers:

- **Tier 1** countries (Denmark, Netherlands, Singapore and Switzerland) are “the most market-oriented systems in the world” because “prescription drug prices are largely or entirely unregulated and/or ... a competitive private insurance market provides the vast majority of coverage.”
- **Tier 2** countries (Austria, Belgium, Czech Republic, France, Germany, Ireland, Japan, Portugal and Slovakia) are described as “countries like the United States with a mix of public and private insurance.”

In constructing the MBII, the report proposes to assign a 60 percent weight to prices in Tier 1 countries and a 40 percent weight to those in Tier 2.

The FREOPP report includes a useful discussion of differences in health care financing among countries that proponents and opponents of proposals like Medicare For All typically describe as having “single payer” systems. The report notes that “not all advanced countries with universal coverage have single payer health care systems.”

It also makes two additional assertions that are critical to its assessment of the proposed Part B drug pricing demonstration project: 1) “not all advanced countries deploy price controls”; and 2) “not all foreign countries have access problems to new medicines.”

### ***Drug Prices in MBII Countries***

A closer look shows that drug prices in Tier 1 countries are generally not market-based and that many new drugs launched between 2011 and 2018 are not available in MBII countries.

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Equal Opportunity, January 11, 2019. <https://freopp.org/what-medicare-can-learn-from-other-countries-on-drug-pricing-bf298d390bc5>

<sup>44</sup> Ibid. As Appendix 2 shows, there is substantial overlap between IPI and MBII countries. Of the 12 MBII countries, eight (Austria, Belgium, Czech Republic, Denmark, France, Germany, Ireland and the Netherlands) are on the IPI list. MBII omits six IPI countries (Canada, Finland, Greece, Italy, Japan and UK) and adds four non-IPI nations (Portugal, Singapore, Slovakia and Switzerland).



Singapore, a Tier 1 country, is a leading example. The government has established a health care financing system in which consumers play an active role. While low-income people rely on MediFund, a government program of medical assistance, medical care for most Singaporeans is financed through MediShield and MediSave.<sup>45</sup> Citizens are automatically enrolled in MediShield, which covers major medical expenses. And they are required through a forced savings program to deposit between 8 and 10.5 percent of their salaries into their MediSave accounts.<sup>46</sup> Consumers use these accounts, which they own, to pay health insurance premiums and medical expenses.<sup>47</sup>

But while Singapore puts consumers in control on the demand side of health care, the government plays an outsize role on the supply side. The government owns more than 80 percent of hospital beds and subsidizes a large share of inpatient care.<sup>48</sup>

The government also sets drug prices and determines which medicines people have access to. The government's health ministry publishes a "standard drug list." Drugs that make the list are available to consumers at subsidized rates. Consumers cannot use their MediSave accounts to purchase drugs the government excludes from the list.<sup>49</sup>

Although Singapore's system is very unlike those of other developed countries, its drug pricing can hardly be said to be market-based.

Denmark is an example of a Tier 1 country that has a single payer system—the government finances health care through an earmarked income tax and hospitals are publicly owned and subject to global budgets<sup>50</sup>—but allows pharmaceutical companies to set their own prices.<sup>51</sup> This freedom, however, is constrained by an agreement between the Danish Association of Pharmaceutical Industry and the government's health ministry to impose price caps on

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<sup>45</sup> Ezra Klein, "Is Singapore's 'Miracle' Health Care System the Answer for America?" Vox, April 25, 2017. <https://www.vox.com/policy-and-politics/2017/4/25/15356118/singapore-health-care-system-explained>

<sup>46</sup> MediSave is one component of the Central Provident Fund (CPF), which is financed through a combination of employer contributions and employee forced savings. The fund contains certain dedicated accounts. In addition to MediSave, CPF proceeds also can be used for retirement, housing and education. "CPF Contributions in Singapore," Moneysmart, April 9, 2018. <https://blog.moneysmart.sg/budgeting/cpf-contributions-singapore-guide-interest-rates-minimum-sum-calculator/>

<sup>47</sup> "MediSave," Singapore Ministry of Health (accessed February 24, 2019). <https://www.moh.gov.sg/cost-financing/healthcare-schemes-subsidies/medisave>

<sup>48</sup> Klein, "Singapore's 'Miracle.'"

<sup>49</sup> Ibid.

<sup>50</sup> Elias Mossialos, Ana Djordjevic, Robin Osborn and Dana Sarnak, International Profiles of Health Care Systems, Commonwealth Fund, May 2017, Tables 1 and 4, pp. 6 and 9. <https://www.commonwealthfund.org/publications/fund-reports/2017/may/international-profiles-health-care-systems>

<sup>51</sup> "Prices of Medicines," Danish Medical Agency, updated July 13, 2015. <https://laegemiddelstyrelsen.dk/en/reimbursement/prices/>





medicinal products.<sup>52</sup> More recently, the Danish Health Ministry announced its intention to propose an external reference pricing system in order to further reduce drug prices.<sup>53</sup> The new system, if adopted, would take effect in 2020.

It is also important to distinguish between pricing policy and reimbursement policy. Since virtually everyone is enrolled in the government system, most Danes rely on the government to pay for the bulk of their medical care, including medicines. If a drug is not included on Denmark's reimbursement formulary, citizens who want or need that drug must pay for it out of their own pockets.

The Danish Medicines Agency decides the reimbursement status of each pharmaceutical product.<sup>54</sup> In making its determination, the agency considers the product's therapeutic value and side effects, among other factors. These include price comparisons, budget impact and other economic evaluations. To assist in this evaluation, companies are encouraged to include pharmacoeconomic assessments of their products in their applications.<sup>55</sup> Pharmacies are obliged to dispense the cheapest alternative with the same active ingredient, with patients paying the difference if they choose a more expensive medicine.<sup>56</sup>

The government plays a much larger role in setting the price of drugs in other Tier 1 countries. The Dutch Minister of Health, Welfare and Sport, for example, sets maximum prices for specific medicines, using prices set in Belgium, Germany, the UK and France as benchmarks.<sup>57</sup> Pharmacies may not purchase products that exceed these prices, and health insurers generally compensate only for the cheapest alternative in a therapeutic category.<sup>58</sup> Beginning in 2015, the government established an additional approval process on a case-by-case basis for more costly medicines, in an attempt to negotiate lower prices

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<sup>52</sup> "Agreement between the Danish Association of the Pharmaceutical Industry (Lif), the Danish Regions and the Ministry of Health and Elderly Affairs on a Cap on the Prices of Medicinal Products." [https://www.lif.dk/SiteCollectionDocuments/Prisloftaftaler/Price-cap%20agreement%20on%20medicinal%20products\\_2016-2018\\_UK\\_Final.pdf](https://www.lif.dk/SiteCollectionDocuments/Prisloftaftaler/Price-cap%20agreement%20on%20medicinal%20products_2016-2018_UK_Final.pdf) These price caps do not apply to over-the-counter products.

<sup>53</sup> Martin Draebye Gantzhorn and Emil Kjeldahl Bjerregaard Bjerrum, "Denmark: Announcement of Proposal on External Reference Pricing (ERP) System on Medicinal Products," Bech-Braun Law Firm, November 7, 2018. <https://www.bechbruun.com/en/news/2018/denmark-announcement-of-proposal-on-external-reference-pricing-erp-system-on-medicinal-products>

<sup>54</sup> "Denmark – Pharmaceuticals." ISPOR, Global Health Technology Assessment Road Map, December 2015, p. 4. <https://tools.ispor.org/htaroadmaps/Denmark.asp>

<sup>55</sup> Ibid, p. 4.

<sup>56</sup> Mossialos, et al., *International Profiles of Health Care Systems*, p. 45.

<sup>57</sup> "A Shift in Discussion on Pricing and Reimbursement of Medicines in the Netherlands," Baker McKenzie, October 26, 2017. <https://www.bakermckenzie.com/en/insight/publications/2017/10/pricing-reimbursement-medicines-netherlands>

<sup>58</sup> Ibid.



with manufacturers.<sup>59</sup> Insurers are not automatically allowed to cover a new drug. The government decides which medicines fall under the standard health insurance package.<sup>60</sup>

Switzerland has a two-step approval process for new drugs—one linked to their safety and efficacy and a second to “functionality and economic efficiency.”<sup>61</sup> The government bases its determination of economic efficiency on comparative prices in nine countries (Germany, Denmark, UK, the Netherlands, France, Austria, Belgium, Finland and Sweden) and on a comparison with other products already on the market.<sup>62</sup> The government then sets the product’s maximum price.

Thus, governments in Tier 1 countries play an active role in setting drug prices and therefore in regulating access to prescription medicines. In Tier 2 countries, a similar pattern prevails (see Appendix 1, which includes a description of drug pricing policies in Tier 2 countries).

The one apparent exception among Tier 2 countries is Germany, where pharmaceutical companies can price newly launched products during their first year on the market. That price is fully reimbursed by German insurance plans for that period.<sup>63</sup>

That nod to market pricing, however, is highly qualified. Simultaneous with the product’s launch, the Federal Joint Committee, which has authority over coverage decisions for all German payers, commissions a clinical comparative effectiveness review by the Institute of Quality and Efficiency of Healthcare.<sup>64</sup> Based on those recommendations and within six months of the product’s introduction, the Federal Committee decides whether the product offers an “added therapeutic benefit” over products already on the market. Using a six-point scale that ranges from “major added benefit” to “lower added benefit than current therapies,” the committee grades the product.

Those products found to offer no added benefit are then reimbursed at the price paid for existing therapies, which can include older generic drugs. Manufacturers that set a higher launch price must pay back insurance funds for the higher reimbursement it received prior to the Federal Committee’s determination.<sup>65</sup>

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<sup>59</sup> Ibid.

<sup>60</sup> “Keeping Medicines Affordable,” Government of the Netherlands. <https://www.government.nl/topics/medicines/keeping-medicines-affordable>

<sup>61</sup> “Pricing and Reimbursement 2018: Switzerland,” Global Legal Insights. <https://www.globallegalinsights.com/practice-areas/pricing-and-reimbursement-laws-and-regulations/switzerland> (accessed January 21, 2019).

<sup>62</sup> Ibid.

<sup>63</sup> Karl Lauerbach, John McDonough and Elizabeth Seeley, “Germany’s Model for Drug Price Regulation Could Work in the US,” Health Affairs Blog, December 29, 2016. <https://www.healthaffairs.org/doi/10.1377/hblog20161229.058150/full/>

<sup>64</sup> Ibid.

<sup>65</sup> Ibid.



If the committee finds that a product does offer an added therapeutic benefit, the manufacturer enters into price negotiations with the National Association of Statutory Health Insurances. If the parties fail to reach an agreement, the matter is submitted to an arbitration panel, which sets the price based on international reference pricing.<sup>66</sup>

Thus, while manufacturers can set their own prices for new drugs, they do so at financial risk. If the government concludes that their drug didn't deliver additional value, then manufacturers must reimburse insurers for the price differential. And even if the government agrees that their product offers superior clinical value compared with drugs previously on the market, they must negotiate its price, with international reference pricing as the backstop.

The MBII list of countries, while more rationally devised than the IPI, does not produce a materially different result. With either index, Medicare reimbursement for physician-administered drugs would largely be based on international reference prices in which the regulatory agency of one government sets drug prices based at least in part on those set by regulatory agencies in other countries. Importing these mutually reinforcing, centralized decisions into Medicare may reduce reimbursement for physician-administered drugs, but the new reimbursement system cannot be said to be based on market prices.

### ***Drug Access in MBII Countries***

The FREOPP report makes a second claim: that MBII countries, particularly those in Tier 1, “enjoy rapid and frequent access to medicines, comparable to that of the United States.” The report attributes this access “to the use of free pricing in these high-access countries.”

The report bases this assertion on a European Observatory on Health Systems and Policies, looking at the average time to market of drugs approved by the European Medicines Agency between 2006 and 2011. The chart shows that some countries (Germany, UK, Denmark and Sweden among them) did a reasonably good job of making most drugs available within 24 months of approval, with more than 80 percent coming to market in that timeframe. But the Netherlands, which is one of only two Tier 1 countries on the chart, does less well. Fewer than 55 percent of approved drugs reached its market within two years of approval, and fewer than 60 percent had become available beyond the two-year window.

Using IQVIA product sales and regulatory agency data, the Pharmaceutical Research and Manufacturers of America (PhRMA) has compiled more recent data on IPI and MBII countries.<sup>67</sup> It looks at the 290 New Active Substances launched in these countries between 2011 and 2018 and compares them with the

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<sup>66</sup> Ibid.

<sup>67</sup> Source: Pharmaceutical Research and Manufacturer Association, using data compiled by IQVIA.



United States. The results for MBII countries are shown in Table 2.

		Tier 1				Tier 2									
	New Active Substances	United States	Denmark	Nether-lands	Singapore	Switzerland	Austria	Belgium	Czech Republic	France	Germany	Ireland	Japan	Portugal	Slovakia
Total	290	89%	57%	56%	29%	48%	60%	43%	36%	48%	62%	40%	50%	43%	39%
Oncology	82	96%	66%	66%	46%	62%	70%	56%	49%	66%	73%	51%	54%	61%	51%

Of the 290 new active substances that became available between 2011 and 2018, 89 percent are available in the United States. That figure drops considerably among MBII countries. In the four Tier 1 countries, the percentage of available drugs ranges from 29 percent (Singapore) to 57 percent (Denmark), with most new drugs being unavailable in Switzerland and Singapore. The range of availability of new drugs is somewhat higher in Tier 2 countries, varying from 36 percent (Czech Republic) to 62 percent (Germany).

Access to new drugs thus appears marginally higher in Tier 2 MBII countries than in Tier 1 countries. This is noteworthy since the proposed MBII reimbursement model would weight drug prices in Tier 1 countries more heavily, given their presumed “use of free pricing” and “rapid and frequent access to medicines, comparable to that of the United States.” These attributes appear to be even less true of Tier 1 countries than of those in Tier 2.

A similar pattern holds for oncology drugs, many of which are administered by physicians and therefore covered under Part B of Medicare. Of the 82 new cancer medications that have been introduced since 2011, 96 percent are available in the United States. For Tier 1 countries, availability varies from 46 percent (Singapore) to 66 percent (Denmark and the Netherlands). New oncology drugs are more likely to be available in Tier 2 countries than in Tier 1 countries, with a range of 49 percent (Czech Republic) to 73 percent (Germany).

No MBII or IPI country affords as rapid and broad access to new treatments as the United States. This casts considerable doubt on the FREOPP report’s observation that “not all foreign countries have access problems to new medicines.” Citizens of MBII and IPI countries do not have rapid and frequent access to prescription drugs comparable to that of the United States.

This diminished access complicates HHS’s task of establishing international reference pricing for its proposed Part B Medicare reimbursement demonstration. In an October 2018 report, HHS analyzed the availability of 27 Part B medicines in 16 countries. It found that





only 11 of those medicines were available in all 16 countries.<sup>68</sup> In its comment letter on the ANPRM, PhRMA stated that just 51 percent of Part B medicines launched between 2011 and 2018 were available in IPI countries.<sup>69</sup>

In computing an international reference price for a Part B drug, CMS will consequently encounter several countries in which the drug may not be available at all. Excluding it from the reference price computation would have a distorting effect. Patients in countries pay at least an implicit cost for their lack of access. Some may travel to countries (including the United States) where the drug is available. Others will bear the cost in the form of adverse outcomes.

IHS Markit recently released a study comparing health outcome differences due to drug access.<sup>70</sup> The study quantified the population health impact in the United States of introducing non-U.S. models of drug access. It specifically looked at outcomes for non-small cell lung cancer (NSCLC) between 2006 and 2017, the leading cause of cancer mortality both in the U.S. and the world.<sup>71</sup> The report compared the drug access models of the U.S. to that of five other countries: Australia, Canada, France, South Korea and the UK. The list includes one MBII country (France) and three IPI countries (Canada, France and the UK).

Access to new NSCLC treatments was much faster in the United States than in these five countries. The authors estimate that Americans with that disease have gained 201,700 life years as a result of faster access to innovative medicines. Had access been similar to that in the five other countries, the U.S. would have lost half those gains, the study found.<sup>72</sup>

## Conclusion

The proposed Part B drug pricing demonstration program raises a variety of concerns, ranging from the constitutional to the technical. In seeking to reduce Medicare drug spending, CMS is embarking on a course that could culminate

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<sup>68</sup> “Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditure,” HHS Office of Assistant Secretary for Planning and Evaluation, October 2018. <https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf>

<sup>69</sup> PhRMA comment letter on CMS-5528-ANPRM; Medicare Program; International Pricing Index Model for Medicare Part B Drugs, December 31, 2018. <https://www.phrma.org/public-communication/phrma-international-pricing-index-model-comments>

<sup>70</sup> Wayne Su and Cameron Lockwood, “Comparing Health Outcome Differences Due to Drug Access: A Model in Non-Small Cell Lung Cancer,” IHS Markit, December 13, 2018. [https://cdn.ihs.com/www/prot/pdf/0119/IHSM\\_NSCLC%20HTA%20model%20white%20paper\\_18Jan2019r.pdf](https://cdn.ihs.com/www/prot/pdf/0119/IHSM_NSCLC%20HTA%20model%20white%20paper_18Jan2019r.pdf)

<sup>71</sup> Ibid, p. 2.

<sup>72</sup> Ibid, p. 2.



the creation of a new reimbursement scheme absent congressional action. This is especially troubling since, for all the different payment methodologies Congress has devised for medical goods and services, it has never based reimbursement on prices that prevail in foreign countries. The agency's role is to implement congressionally-established reimbursement systems, not to create them out of whole cloth. CMS's reliance on a constitutionally-suspect mechanism will invite litigation, creating a climate of uncertainty for patients and providers.

In addition to constitutional infirmities, the proposed demonstration raises serious policy concerns. Comparing health care prices across countries is a complicated undertaking. Such comparisons must take into account economic and cultural differences, as well as America's unique methods of health care financing, which grew and evolved in ways that differ markedly from those in Europe.<sup>73</sup> In outlining the proposed demonstration project, the agency has evidenced no appreciation for these differences. Its criteria for selecting foreign countries lacks a coherent guiding principle, and it has not factored in a matter of paramount concern to beneficiaries and, arguably, to policymakers: Many Part B drugs are not available in IPI countries.

The FREOPP study offers a more cogent rationale for selecting countries for a reference pricing regime than does HHS. A closer analysis, however, reveals that drug prices in the MBII countries are generally not market-based. Nor is it clear how the market price for a drug in Singapore or Slovakia would relate to the market price in the United States, especially given differences in living standards and consumption patterns. Moreover, although the paper asserts that "not all foreign countries have access problems to new medicines," the evidence suggests that such problems exist in both MBII and IPI countries.

None of this, of course, suggests that the ASP+6 methodology is ideal or even good. While it is intended to capture actual prices paid in the marketplace, net of discounts, rebates and other price concessions, the FREOPP paper identifies a number of problems with the methodology. Congress has left this system unamended for more than 15 years. It is worth revisiting.

The FREOPP paper at one point suggests that Congress should "allow seniors to choose among multiple plans that compete on price to deliver the Part B benefit." The paper correctly observes that this would facilitate "vigorous price competition among private insurers to deliver prescription drug coverage."

Such a market-based approach, which is the leading characteristic of Part D drug coverage, differs markedly from the administered pricing system on which the rest of Medicare relies. Those various administered pricing regimes have produced repeated policy failures, even when they seek to mimic market prices.<sup>74</sup>

Letting markets set Medicare prices for drugs and other medical goods and services is a fruitful path for Congress to explore.

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<sup>73</sup> For a fuller discussion of these differences, see Doug Badger, "Replacing Employer-Sponsored Health Insurance with Government-Financed Coverage," Galen Institute, November 27, 2018. <https://galen.org/2018/replacing-employer-sponsored-insurance-with-government-financed-coverage-considerations-for-policymakers/>

<sup>74</sup> See, for example, Doug Badger, "Can Medicare Pay Market Rates?" Galen Institute, July 24, 2018. [https://galen.org/assets/Can\\_Medicare\\_Pay\\_Market\\_Rates\\_Badger\\_072418-1.pdf](https://galen.org/assets/Can_Medicare_Pay_Market_Rates_Badger_072418-1.pdf)



## Appendix 1. Drug Pricing Policies in Tier 2 MBI Countries

**Austria.**<sup>75</sup> The Association of Austrian Social Security Institutions is responsible for deciding whether to reimburse for a medicine, based on pharmacological, medical-therapeutic and health-economic evaluation. The national health insurance system only reimburses for products that the Association includes in its Reimbursement Code. The Association assigns drugs to either a red, yellow or green box. All newly approved products are automatically assigned to the red box for a period of up to 180 days. If the association has not assigned an Average European Price (AEP) for the product, then the manufacturer can establish the reimbursement price for the product during this period. However, if an AEP is subsequently established, then the manufacturer has to reimburse the difference between the AEP and the established price. All products that are determined to add significant therapeutic value are assigned to the yellow box and reimbursed at AEP. Products in the green box can only be reimbursed if their use is medically and economically justified. If products with similar therapeutic effects already are listed, the new green box product is only reimbursed if its price differs significantly from existing products.

**Belgium.** Belgium's compulsory health insurance system only reimburses for drugs that the government includes on its list of reimbursable products.<sup>76</sup> In order for a product to be included on this list, its manufacturer must obtain the approval of both the Ministry of Economic Affairs, which sets the product's maximum price, and the Ministry of Social Affairs and Public Health, which sets the reimbursement rate.<sup>77</sup>

**Czech Republic.** The government of the Czech Republic sets pharmaceutical prices and reimbursement levels. Maximum price is generally set at the mean of the three lowest prices in the European Union reference basket.<sup>78</sup> Reimbursement is set at the lowest price of any medicine within the product's therapeutic category, which can include older generic medicines. The government's National Institute for Health and Clinical Care Excellence employs a strict cost-utility analysis to limit the budgetary impact of costly drugs and insurance funds separately negotiate risk-sharing schemes for drugs whose price exceeds certain threshold levels.<sup>79</sup>

**France.** The Economic Committee on Medicinal Products sets drug prices based on a variety of factors. These include economic and medical studies, as well as the prices of other drugs in the same therapeutic category.<sup>80</sup>

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<sup>75</sup> "Pricing and Reimbursement 2018: Austria," Global Legal Insights. <https://www.globallegalinsights.com/practice-areas/pricing-and-reimbursement-laws-and-regulations/austria#chaptercontent3>

<sup>76</sup> "Pricing and Reimbursement 2018: Belgium," Global Legal Insights. <https://www.globallegalinsights.com/practice-areas/pricing-and-reimbursement-laws-and-regulations/belgium> (Accessed January 21, 2019).

<sup>77</sup> Ibid.

<sup>78</sup> J. Skoupa, "Drug Policy in the Czech Republic," Value Health Reg Issues, September 2017, NCBI. <https://www.ncbi.nlm.nih.gov/pubmed/29073989>

<sup>79</sup> Ibid.

<sup>80</sup> "Pricing and Reimbursement 2018: France," Global Legal Insights. <https://www.globallegalinsights.com/practice-areas/pricing-and-reimbursement-laws-and-regulations/france> (Accessed January 21, 2019).



**Germany.** *See discussion in the body of the paper.*

**Ireland.** The Irish government regulates prices of new medicines to not exceed the average prices in 14 other countries.<sup>81</sup> All drugs are then subject to mandatory, annual price realignments to reflect pricing changes in these other countries. In addition, manufacturers are required to pay the government monthly rebates on 5.5% of their sales revenue. When a biosimilar is introduced, the price of the innovator product is reduced by 20 percent.

**Japan.** The Japanese government sets the prices of new drugs reimbursed by National Health Insurances.<sup>82</sup> There are multiple pricing pathways for new drugs. Those that are similar to drugs already listed and offer “little novelty” are reference priced to existing drugs, subject to an adjustment for foreign prices.<sup>83</sup> In other cases, drugs may be eligible for various “premiums” for innovation, value or marketability.<sup>84</sup> In the case of a new drug for which no similar product is listed, the price is set based on various costs (manufacture or import, other expenses, operating profit, distribution cost, consumption taxes, etc.), adjusted to align with foreign prices.<sup>85</sup> These initial reimbursed prices are then cut by several percentage points every two years based on actual purchase prices paid by medical institutions and pharmacies. Prices are also adjusted downward for drugs that exceed sales forecasts, including when a drug is approved for new indications, or based on company criteria that disadvantages companies with less domestic investment.<sup>86</sup>

**Portugal.** The government sets a maximum price of a drug based on its lowest price in three countries selected based on price levels in those countries and their similarity to Portugal’s GDP.<sup>87</sup> The government also sets targets for overall pharmaceutical expenditures.

**Slovakia.** The government sets prices and reimbursement levels for prescription drugs which are among the lowest in Europe.<sup>88</sup> All drugs have a government-set maximum manufacturer (or importer) price that cannot exceed the average of the three lowest-priced countries in Europe. The government also sets margins for wholesalers and pharmacies.<sup>89</sup>

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<sup>81</sup> “The New Agreement on the Supply and Pricing of Medicines Explained,” Policy.IE, October 10, 2016. <http://www.publicpolicy.ie/the-new-agreement-on-the-supply-and-pricing-of-medicines-explained/>

<sup>82</sup> Masanobu Yamate, “Update of Drug Pricing System in Japan,” Ministry of Health, Labor and Welfare, p. 7. <https://www.pmda.go.jp/files/000221888.pdf>

<sup>83</sup> *Ibid*, p. 12.

<sup>84</sup> *Ibid*, p. 12.

<sup>85</sup> *Ibid*, p. 12.

<sup>86</sup> *Ibid*, p. 33.

<sup>87</sup> “Health Systems in Transition: Portugal,” Health Systems and Policy Monitor, European Observatory on Health Systems and Policies, last updated September 2017. <https://www.hspm.org/countries/portugal25062012/livinghit.aspx?Section=5.6%20Pharmaceutical%20care&Type=Section>

<sup>88</sup> Maria Bucek Psenkova, et al., “Drug Policy in Slovakia,” Value in Health Regional Issues 13C, Science Direct, 2017, p. 46. <https://www.hspm.org/countries/portugal25062012/livinghit.aspx?Section=5.6%20Pharmaceutical%20care&Type=Section>

<sup>89</sup> *Ibid*, p. 47.





## Appendix 2. Percent of New Active Substances Available: U.S. vs. MBII, IPI and ASPE Countries (2011-2018)

				Total New Active Substances	Anti-infectives and Antivirals	Blood	Cardiovascular	Central Nervous System	Dermatology	Diabetes	Gastrointestinal	Genitourinary and Hormones	Immune System	Metabolic	Musculoskeletal	Oncology	Ophthalmologics	Respiratory	Other	
	<b>New Active Substances</b>			<b>290</b>	41	21	11	27	11	16	11	10	7	15	9	82	8	11	10	
<b>United States</b>				<b>89%</b>	90%	100%	91%	89%	91%	63%	73%	90%	86%	87%	67%	96%	75%	100%	80%	
	<b>Country Groupings</b>																			
	IPI*	MBII**	ASPE***																	
<b>Austria</b>	X	Tier 2	X	<b>60%</b>	66%	67%	73%	41%	64%	50%	45%	30%	86%	47%	67%	70%	13%	82%	40%	
<b>Belgium</b>	X	Tier 2	X	<b>43%</b>	44%	52%	55%	26%	36%	44%	18%	20%	71%	20%	33%	56%	25%	64%	20%	
<b>Canada</b>	X		X	<b>44%</b>	46%	14%	73%	33%	64%	50%	36%	20%	43%	13%	33%	59%	50%	73%	10%	
<b>Switzerland</b>		Tier 1		<b>48%</b>	51%	48%	64%	41%	45%	50%	36%	30%	71%	0%	44%	62%	13%	64%	30%	
<b>Czech Rep</b>	X	Tier 2	X	<b>36%</b>	34%	29%	45%	22%	27%	44%	18%	30%	71%	13%	11%	49%	25%	55%	20%	
<b>Germany</b>	X	Tier 2	X	<b>62%</b>	63%	67%	73%	48%	64%	56%	36%	50%	86%	53%	56%	73%	38%	82%	40%	
<b>Denmark</b>	X	Tier 1		<b>57%</b>	61%	71%	55%	44%	55%	56%	45%	20%	86%	33%	44%	66%	25%	73%	50%	
<b>Spain</b>			X	<b>14%</b>	15%	5%	18%	22%	9%	31%	9%	20%	14%	0%	0%	13%	13%	36%	10%	
<b>Finland</b>	X		X	<b>52%</b>	59%	43%	55%	44%	45%	44%	45%	30%	86%	33%	44%	65%	25%	73%	30%	
<b>France</b>	X	Tier 2	X	<b>48%</b>	59%	43%	45%	41%	36%	19%	27%	30%	71%	33%	44%	66%	13%	55%	30%	
<b>Greece</b>	X		X	<b>14%</b>	10%	10%	18%	19%	18%	44%	9%	20%	14%	0%	0%	11%	13%	36%	10%	
<b>Ireland</b>	X	Tier 2	X	<b>40%</b>	54%	14%	55%	22%	36%	44%	27%	30%	86%	20%	22%	51%	13%	64%	20%	
<b>Italy</b>	X		X	<b>52%</b>	59%	52%	64%	44%	27%	44%	27%	40%	86%	53%	44%	57%	38%	64%	40%	
<b>Japan</b>	X		X	<b>50%</b>	51%	57%	73%	26%	64%	81%	45%	30%	57%	27%	56%	54%	25%	64%	40%	
<b>Netherlands</b>	X	Tier 1		<b>56%</b>	59%	67%	73%	52%	64%	50%	36%	30%	86%	27%	56%	66%	25%	73%	20%	
<b>Portugal</b>		Tier 2		<b>43%</b>	49%	29%	55%	26%	27%	25%	18%	30%	71%	40%	22%	61%	25%	64%	30%	
<b>Sweden</b>			X	<b>54%</b>	61%	43%	64%	52%	45%	56%	45%	30%	86%	33%	44%	62%	25%	82%	40%	
<b>Singapore</b>		Tier 1		<b>29%</b>	34%	14%	45%	11%	9%	31%	9%	0%	43%	0%	22%	46%	13%	45%	20%	
<b>Slovakia</b>		Tier 2	X	<b>39%</b>	41%	43%	55%	30%	27%	44%	18%	30%	71%	7%	33%	51%	13%	55%	10%	
<b>United Kingdom</b>	X		X	<b>60%</b>	66%	48%	73%	56%	55%	50%	45%	30%	86%	40%	56%	71%	38%	82%	50%	

Source: Pharmaceutical Research and Manufacturers Association, using data compiled by IQVIA.

\*IPI countries were selected by CMS in its advance notice of proposed rulemaking, 83 FR 54546, October 30, 2018. <https://www.govinfo.gov/content/pkg/FR-2018-10-30/pdf/2018-23688.pdf>

\*\*MBII countries were selected in a paper entitled, "What Medicare Can Learn About Drug Prices from Other Countries." The report breaks countries into two tiers, which are indicated on the table. <https://freopp.org/what-medicare-can-learn-from-other-countries-on-drug-pricing-bf298d390bc5>

\*\*\*ASPE countries were selected by the HHS Assistant Secretary for Planning and Evaluation in a report entitled, "Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditure." <https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf>