McDermott Will & Emery

McDermott+ Consulting

Trump Administration Announces Most-Favored Nation Drug Pricing Model

POLICY UPDATE: DRUG PRICING

International Reference Pricing in the United States: Implications for US and International Pharmaceutical Market

McDermott Will & Emery

McDermott+ Consulting

TABLE OF CONTENTS

INTRODUCTION

Drug prices have emerged as an important US political issue in recent years, with roughly 140 bills on drug prices introduced in the US Congress since January 2019. On November 20, 2020, the US Department of Health and Human Services (HHS) announced an interim final rule with comment that will introduce sweeping changes to the way many drugs are reimbursed by Medicare Part B in the United States by adopting a system of external reference pricing (ERP) using a "most-favored nation" (MFN) pricing approach. With a change in administration on January 20, 2021, and potential legal challenges on the horizon, it is uncertain whether this rule will be implemented as published. There is bipartisan interest in drug pricing legislation with an ERP approach having support across the political aisle. This suggests that even if the MFN interim final rule is not implemented as published, an ERP approach may likely be a part of future policymaking on ratesetting for drugs under Medicare.

While the direct intent of the MFN model are savings on drug expenditures for the Medicare program and for US patients, there may be significant spillover effects in the global marketplace that could potentially alter the order of entry into global healthcare markets, or even affect the decision whether to enter some markets at all. Currently, ex-US pricing and reimbursement frameworks generally do not constrain US pricing and reimbursement nor do the ex-US marketplaces generally impact whether or when pharmaceuticals are introduced in the US. With implementation of the MFN model, however, given the size and wealth of the United States, pharmaceutical companies will need to consider the ex-US marketplace—including relatively small marketplaces—when considering pricing applicable to the US and vice versa.

Stakeholders should consider both short- and long-term strategies to respond to the MFN. Short-term response options include advocacy while the rule is open to comment as well as potential legal challenges by those with standing to challenge the rule. In the long term, stakeholders should plan for the possibility that an ERP policy will persist in some form and consider the potential impact on availability, access, and pricing for pharmaceuticals in the US and outside the US.

With the publication of the MFN model interim final rule, below we review ERP proposals in the United States, drug pricing regimes in several other Organization for Economic Cooperation and Development (OECD) countries, and the implications of implementation of an ERP regime in the United States for global pharmaceutical market entry.

Important links:

- MFN model news release
- MFN rule
- MFN model website

DOMESTIC US MEDICARE DRUG RATESETTING POLICY

EXISTING POLICY AND CHANGES UNDER THE MFN MODEL

Under current US drug pricing laws, Medicare generally pays average sales price (ASP) plus 6% for drugs billed under Medicare Part B, which includes a limited group of drugs, primarily physician-administered drugs and infusion drugs administered through durable medical equipment. Medicare Part D plans cover outpatient prescription drugs. Medicare does not establish rates for drugs covered by Medicare Part D plans, but health insurers offering the plans and their benefit managers have had the ability to negotiate discounts and rebates from manufacturers.

The MFN model is a seven-year mandatory "model" with a four-year phase-in period involving the entire nation, and will set the reimbursement rate of a list of generally high-expenditure drugs equal to the lowest adjusted price from a market basket of other nations (i.e., the MFN price). The market basket will be composed of OECD nations with a per-capita GDP of at least 60% of that of the United States. Rate adjustment will be based on relative per-capita GDP. The current drug list includes 50 drugs, although drugs may be added over the next seven years as new drugs make it into the top 50 on total expenditures. Rates will be updated quarterly based on international drug prices preferentially obtained from current volume and price data, although alternative data sources may be used when this data is not available. The table below shows model MFN pricing data, adapted from the rule, for an example country.

The MFN model currently includes a market basket of 22 countries (Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Iceland, Ireland, Israel, Italy, Japan, Republic of Korea, Luxembourg, Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland and the United Kingdom) and could potentially include up to 36 additional countries (the total count of OECD members excluding the United States). The MFN model thus will use one of the largest market baskets among countries in the OECD that use a market-basket ERP regime. Large market baskets are often selected by a country when the pricing goal is to minimize sensitivity to outlier prices. However, the MFN model will, by design, select the low outlier price from this large basket.

Central to the MFN model is the issue of what the MFN model (or any ERP model) considers to be a "price" in the external reference basket. Timely data that reflect the settlement prices of real transactions are the most meaningful representations of the prices foreign markets are willing to bear. The MFN model recognizes this, placing recent transaction data that includes both price and volume at the top its data-source hierarchy. However, when recent transaction data are unavailable for a country, the MFN model will use older transaction data and, in the absence of data reflecting transactions, will resort to using the list price in a country. This means that there are different strategic and financial planning considerations between drugs that already have transaction data available in OECD countries, including the drugs already selected for MFN model inclusion, and drugs that have not yet been introduced to the global marketplace and have not yet been included in the MFN model.

HHS appears to be aware that the MFN model may have domestic healthcare implications in other OECD countries, noting that countries may leave the OECD to avoid having their drug prices tied to the United States. The rule notes that OECD membership on October 1, 2020, will be used to define the countries considered OECD members going forward.

CMS bases its authority to bypass the current statutory framework for Part B drug rate-setting from its authority to implement cost savings models under the Center for Medicare and Medicaid Innovation.

Key Takeaway: On average, the MFN price generally represents a significant discount to the ASP.

In 2021, the MFN drug payment amount will be 75% weighted on the ASP (as reported by the manufacturer in the US) and 25% weighted on the MFN price. In each of the subsequent 3 years of the model, the MFN drug payment will be weighted 25% more heavily on the MFN price until the model bases rates on 100% of the MFN price for years 4 through 7 of the model. Data shown below are adapted from Table 6 in the rule. The Illustrative MFN Drug Payment Amount is a blending of the applicable ASP and the MFN price representative of the first year of the phase-in period (2021). The MFN price is, on average, 33% of the ASP.

Illustrative Drug Payment Amounts for First Year of Model (2021) using 2019 Q1 Data					
HCPCS Code	Short Description	Illustrative Applicable ASP	Illustrative MFN Price	Illustrative MFN Drug Payment Amount	Illustrative MFN Country
J0129	Abatacept injection	$50.89	$12.98	$41.41	Australia
J0178	Aflibercept injection	$903.17	$399.36	$777.22	Norway
J0517	Inj., benralizumab, 1 mg	$159.28	$102.88	$145.18	Germany
J0585	Injection, onabotulinumtoxina	$5.78	$1.11	$4.61	United Kingdom
J0717	Certolizumab pegol inj 1mg	$7.67	$1.92	$6.23	Australia
J0881	Darbepoetin alfa, non-esrd	$3.61	$0.83	$2.91	Republic of Korea
J0885	Epoetin alfa, non-esrd	$10.81	$3.09	$8.88	Republic of Korea
J0897	Denosumab injection	$18.02	$2.96	$14.26	Norway
J1300	Eculizumab injection	$217.43	$161.47	$203.44	United Kingdom
J1439	Inj ferric carboxymaltos 1mg	$1.03	$0.02	$0.78	Japan
J1602	Golimumab for iv use 1mg	$20.82	$14.78	$19.31	Republic of Korea
J1745	Infliximab not biosimil 10mg	$61.20	$27.43	$52.76	Austria

Illustrative Drug Payment Amounts for First Year of Model (2021) using 2019 Q1 Data					
HCPCS Code	Short Description	Illustrative Applicable ASP	Illustrative MFN Price	Illustrative MFN Drug Payment Amount	Illustrative MFN Country
J1930	Lanreotide injection	$59.63	$9.74	$47.16	Norway
J2182	Injection, mepolizumab, 1mg	$28.34	$11.77	$24.20	Sweden
J2323	Natalizumab injection	$19.14	$4.17	$15.40	Australia
J2350	Injection, ocrelizumab, 1 mg	$54.17	$18.79	$45.32	Switzerland
J2353	Octreotide injection, depot	$193.10	$27.52	$151.71	Spain
J2357	Omalizumab injection	$34.96	$10.37	$28.81	Norway
J2505	Injection, pegfilgrastim 6mg	$4,270.57	$780.55	$3,398.07	Germany
J2507	Pegloticase injection	$2,344.57	N/A	2,344.57	N/A
J2778	Ranibizumab injection	$337.12	$31.07	$260.60	Republic of Korea
J2785	Regadenoson injection	$55.92	$19.85	$46.90	United Kingdom
J2796	Romiplostim injection	$69.34	$28.03	$59.02	Japan
J3262	Tocilizumab injection	$4.65	$0.88	$3.71	Australia
J3357	Ustekinumab sub cu inj, 1 mg	$179.91	$40.63	$145.09	France
J3380	Injection, vedolizumab	$18.99	$6.87	$15.96	France
J7324	Orthovisc inj per dose	$138.59	$11.50	$106.82	Japan
J9022	Inj, atezolizumab,10 mg	$72.81	$42.14	$65.14	Germany
J9034	Inj., bendeka 1 mg	$22.45	$0.47	$16.96	Germany
J9035	Bevacizumab injection	$76.68	$29.54	$64.90	Norway
J9041	Inj., velcade 0.1 mg	$42.01	$14.84	$35.22	Canada
J9042	Brentuximab vedotin inj	$153.84	$76.89	$134.60	United Kingdom
J9047	Injection, carfilzomib, 1 mg	$35.14	$17.14	$30.64	Switzerland
J9055	Cetuximab injection	$58.60	$21.42	$49.30	Belgium

Illustrative Drug Payment Amounts for First Year of Model (2021) using 2019 Q1 Data					
HCPCS Code	Short Description	Illustrative Applicable ASP	Illustrative MFN Price	Illustrative MFN Drug Payment Amount	Illustrative MFN Country
J9145	Injection, daratumumab 10 mg	$50.71	$47.05	$49.80	Japan
J9173	Inj., durvalumab, 10 mg	$70.62	$61.52	$68.34	Germany
J9176	Injection, elotuzumab, 1mg	$6.12	$3.89	$5.57	Germany
J9217	Leuprolide acetate suspnsion	$216.53	$81.56	$182.78	Belgium
J9228	Ipilimumab injection	$144.40	$80.86	$128.51	Germany
J9264	Paclitaxel protein bound	$11.61	$0.13	$8.74	Australia
J9271	Inj pembrolizumab	$46.78	$23.31	$40.91	Switzerland
J9299	Injection, nivolumab	$26.23	$8.32	$21.75	Japan
J9305	Pemetrexed injection	$65.61	$1.92	$49.69	Canada
J9306	Injection, pertuzumab, 1 mg	$11.56	$6.19	$10.22	Australia
J9311	Inj rituximab, hyaluronidase	$41.81	$11.66	$34.27	Norway
J9312	Inj., rituximab, 10 mg	$89.60	$22.64	$72.86	Norway
J9354	Inj, ado-trastuzumab emt 1mg	$29.52	$18.76	$26.83	Canada
J9355	Inj trastuzumab excl biosimi	$100.92	$21.92	$81.17	Republic of Korea
Q2043	Sipuleucel-t auto cd54+	$41,532.64	N/A	$41,532.64	N/A
Q5111	Injection, udenyca 0.5 mg	$337.85	$65.05	$269.65	Germany

OTHER RECENT ERP PROPOSALS IN THE UNITED STATES

Key Takeaway: The MFN model is just one of several proposals in the United States to benchmark Medicare drug rates to international prices.

The MFN model is the first ERP scheme to be put forth as a future effective policy. However, even if this particular scheme is not actually implemented as published, it is unlikely to mean the end of the ERP discussion in the United States. Other ERP proposals have been brought forward in the past several years.

Trump Administration 2018 proposal for a limited international pricing indexing model

The Trump administration published an advance notice of proposed rulemaking on October 31, 2018, that outlined a conceptual framework for a payment model under the Center for Medicare and Medicaid Innovation for drugs reimbursed under Medicare Part B based on an international price index. The advance notice of proposed rulemaking gave no explicit decisions on a future model, but CMS expressed an intent to set the price of drugs that represented a high cost to the Medicare program equal to the average of an international price based on a market basket of 16 other countries. While the specific drugs to be included in the model were not determined, CMS referenced its study on international drug prices and chose to examine 27 drugs of interest.

House Democrats' proposal, H.R. 3

The Democrat-controlled US House of Representatives passed H.R. 3 on December 12, 2019, instructing CMS to negotiate drug prices for both Medicare Part B and Medicare Part D. International price indexing would be used as a component of negotiation to set a maximum price. The maximum target price would be 120% of the average price in Australia, Canada, France, Germany, Japan and the United Kingdom. If such information is not available, the maximum target price would be 85% of the US average manufacturer price. Negotiation requirements would not apply to all drugs, but to insulin products and to at least 25 single-source, negotiation-eligible high-expenditure drugs for 2023 and at least 50 for 2024. This bill has not passed the Republican-controlled US Senate to become law.

Biden/Harris platform

President-elect Joseph Biden has addressed drug prices in his political platform. He has not proposed a specific plan to bring down drug prices, but he has indicated support for using ERP based on international drug prices to control prices for novel drugs without competition.

DRUG-PRICING REGIMES IN OECD COUNTRIES

For many other countries, the method of drug pricing is fundamentally a matter of benchmarks to which that drug will be compared. In many countries, novel drugs tend to be benchmarked against external reference prices, while drugs that have been on the market for a while or are similar to existing drugs are benchmarked against internal reference prices.

EUROPEAN DRUG PRICING AND MARKET ENTRY

Key Takeaway: European pricing regimes and market baskets of countries using ERP affect order of entry in Europe.

Europe has a patchwork of drug-pricing approaches that differ by country, but most European countries incorporate ERP into drug-pricing policy in some manner. External price references are based on a market basket of other European countries. The construction of market baskets in each country as well as country-specific price policy has important implications when a manufacturer is deciding the sequence in which to enter each European country. France is the most commonly included country in the reference basket for other European nations, making it an

important country in price setting throughout Europe. As discussed below, drug companies often find it advantageous to enter the German market prior to seeking reimbursement in France. These two countries are also among the largest in Europe, giving them substantial importance in terms of of sales volume.

The United Kingdom is frequently referenced in the market baskets of other countries, although the United Kingdom itself does not use ERP, instead relying on technical and health economic assessments. Manufacturers may make a strategic decision to delay entry into European countries that are commonly used as reference models. Norway, which is not commonly considered in the market baskets of other countries that use ERP, has a dual-pricing approach in which ERP is used to set a maximum legal sale price of a drug, but the actual price of the drug is often lower due to negotiations and a need to achieve cost-effectiveness for national insurance coverage.

Below are summaries of the drug pricing approaches of selected European countries.

Germany

Manufacturers may be paid an asking price for new drugs in Germany for the first year that they are on the market. During the first year that a drug is available in Germany, determinations are made about the efficacy of the drug and how much benefit it offers over alternatives. In general, drugs that are found to offer no significant benefit are priced comparably to existing drugs. Drugs that offer a significant benefit undergo a price negotiation that is informed by the drug prices in 15 other countries, including France; no single formula determines the final price. While some drugs may withdraw from the German market after the first year if they are found to offer no significant benefit, Germany is generally an attractive market for drug launch in Europe because of the manufacturer's ability to freely determine the price for the first year, in conjunction with the effect that the German price has on other countries that use international reference pricing.

France

In France, only innovative drugs are assigned a price that takes into account an ERP, among other factors. This ERP comes from a basket of international prices that includes prices from Germany, the United Kingdom, Italy and Spain. Non-innovative drugs are priced equal to or less than comparable drugs already available, and the overwhelming majority of new drugs in the French market are considered non-innovative.

This makes it attractive for drugs to enter the French market only after establishing a price in typically higher-price markets, such as Germany, in order to support the French price, which also serves as a reference price for several other countries.

United Kingdom

A key feature of the UK drug pricing market is the market power of the state-funded national health service (NHS). The NHS funds the vast majority of drugs prescribed to patients in the United Kingdom. The United Kingdom does not use reference pricing to set drug prices, but it is commonly used as a reference country by other jurisdictions, which can in turn have implications for the prices, discounting or timing of the release of drugs in the United Kingdom.

The United Kingdom is sometimes described as having a "free pricing" regime. In practice, however, there is an extensive set of policy and statutory measures to control drug prices and overall drug spend and profitability. Funding and reimbursement of NHS drugs is generally subject to a cost-effectiveness appraisal by the National Institute for Health and Care Excellence (NICE) against thresholds based on quality-adjusted life years. A positive NICE appraisal triggers a legal obligation for the NHS to fund the drug at the relevant assessed price. When a product does not meet NICE's cost-effectiveness criteria, a drug may still be funded through a "patient access scheme" or other policy exception routes.

Separately, in 2019 the United Kingdom adopted a voluntary scheme with the pharmaceutical industry that is negotiated through trade bodies and other voluntary-scheme members. The voluntary scheme, together with a separate statutory scheme, caps the sales of branded drugs at an agreed level of growth each year, with sales growth above these levels triggering a rebate payment (5.9% in 2020) to the Department of Health and Social Care. A key change in 2019 was an exemption for certain active substances and certain medical indications from rebate payments in order to encourage manufacturers to develop and market drugs in the United Kingdom. A separate regime applies for unbranded or generic drugs, which are largely prescribed in out of hospital settings and are reimbursed against a published drug tariff.

The actual drug price paid by an NHS hospital may vary from the reference or list price through commercial arrangements procured under public tenders or through separate commercial agreements, which may include discounts and further rebates.

The UK government is preparing for potential medication supply disruptions due to Brexit. However, it is too early to determine if Brexit will have a longer-term impact on drug supply or prices in the United Kingdom.

Norway

Norway sets price ceilings on all prescription drugs in the country, but the decision whether the public health insurance system will pay for a drug is a separate process from that followed when setting the price ceiling. The price ceiling is set based on international referencing, although manufacturers may charge a lower price than this ceiling to have the drug covered by Norway's national health insurance.

Before a drug manufacturer can market a new prescription medication in Norway, the Norwegian Medicines Agency (NoMA) must set a maximum pharmacy purchase price and a pharmacy markup cap. This maximum price is generally set at the mean of the three lowest market prices from the following reference basket: Sweden, Finland, Denmark, Germany, the United Kingdom, Ireland, the Netherlands, Belgium and Austria.

The national health insurance system covers all Norwegians, giving it significant market power. In general, the insurance system pays for drugs for significant chronic diseases. The decision regarding whether to cover the cost of a drug is based on a health technology assessment. This assessment considers the quality of life and life years gained versus lost from the availability of the treatment versus non-availability, and the resource needs associated with the treatment. A pharmacoeconomic evaluation is a critical component of the decision whether to cover the cost of the

drug, and marketing the drug below the price ceiling may be necessary in order for the drug to meet pharmacoeconomic coverage criteria.

Because NoMA's methodology for performing a pharmacoeconomic evaluation includes a cost per quality-adjusted life-year calculation, drugs used to treat older patient populations may need to be marketed at lower prices than drugs with comparable effectiveness in younger populations.

ASIA-PACIFIC REGION DRUG PRICING AND MARKET ENTRY

Key Takeaway: Countries in the Asia-Pacific region have been making efforts to reduce drug prices.

While China is the largest country in the world by population and has shown immense economic growth for decades, it is not a member of the OECD. The international community generally does not consider the method for drug pricing in China to be transparent. Both the Republic of Korea (South Korea) and Japan also have large economies and have well-established drug pricing systems for their respective national health insurance systems. Australia is one of the first countries in the world to consider broad economic implications of pharmaceutical costs.

Japan

Prior to assigning a price, Japan's national insurance system evaluates new drugs to determine whether comparable drugs exist. For a drug that has no good comparison, the national insurance system assigns a payment based on manufacturing, operating and development costs, with a profit margin that can be vary significantly based on the perceived novelty and benefit of the drug. This price is compared with the average overseas price (AOP) in a market basket composed of the United States, the United Kingdom, Germany and France. For drugs that cost more than 125% of the AOP, a downward adjustment is made using a formula to move the price closer to the AOP. For drugs that cost less than the AOP, an upward adjustment is made with a formula to move the price closer to the AOP.

With its large economy and a pricing model that has permitted price premiums for novel drugs, Japan has generally been an attractive market in which to launch new drugs early. However, over the past few years Japan's health ministry has been attempting to reduce pharmaceutical spending. This has resulted in significant uncertainty about pricing in the future. We have already seen the Japanese health ministry break from its traditional two-year price update cycle to reduce costs of high-price medications. Moreover, given that the official price determination process already permits some subjectivity in choosing appropriate comparators for determining novelty of a treatment and price benchmarks, it is possible that attitude changes within the health ministry could drive price reductions even in the absence of any official policy change.

The Republic of Korea (South Korea)

The Republic of Korea's pharmaceutical reimbursement scheme previously was similar to that of the United States, in that drugs approved for sale in the country were reimbursed by the national health insurance program based on rates largely driven by the drug makers themselves. A 2006 change in the law reflected a deliberate attempt to curb rising drug prices with the development of a positive listing system in which the national health insurance program

had to evaluate each drug and determine a price to pay for it before it would be covered. Prices are now negotiated between the drug maker and the national health insurance plan. A pharmacoeconomic analysis is one consideration in determining a drug price during these negotiations, but not the only consideration. For drugs that are thought to be comparable to existing drugs, cost effectiveness is evaluated in relation to existing drugs. For drugs for which no alternative is considered to exist, the price in a market basket of seven countries (including the United States, Japan, the United Kingdom, Germany, France, Switzerland and Italy) is considered in the price negotiations.

Australia

Australia was the first country to formally require a pharmacoeconomic analysis of a drug prior to the national health insurance system reimbursing the cost of a drug, a practice it maintains to this day. Drugs that are approved for marketing within Australia are evaluated for clinical benefit, comparability to other drugs and other treatments, cost effectiveness and anticipated overall cost burden. There are no caps on expenditures, but the current pharmacy benefits scheme publicizes the importance of economic sustainability of drug expenditures. In general, among a group of drugs that the pharmacy benefits scheme considers comparable, the national insurance will provide reimbursement in line with the lowest cost drug in that group. There are also statutory requirements for price reductions at five-year anniversaries for coverage of the drug.

GLOBAL MARKET ACCESS STRATEGY CHANGES FOLLOWING US ADOPTION OF ERP PRICING REGIME

Key Takeaway: Adoption of the MFN model in the United States will affect pharmaceutical market entry strategies in countries previously insulated from the US healthcare system.

ERP and selection of market baskets can affect the order of market entry and whether drug makers choose to enter some markets at all. In countries that have longstanding pricing systems and ERP reference baskets, the global pharmaceutical market has had a chance to equilibrate. However, the US pharmaceutical market has been insulated from drug prices in other OECD nations. As such, manufacturers have not needed to significantly consider the impact on US pricing when entering markets in other regions of world. With the implementation of the MFN model, comprising a large market basket and relying on a single outlier low price, the largest payer in the world's largest economy may adopt the price from a country that previously had a low or modest impact on net global drug expenditures. Several non-European OECD nations reference US pricing as part of their market basket in their domestic ERP drug pricing schemes. The MFN model therefore may create an economic shock to the global pharmaceutical market.

For example, Norway, which has substantially lower drug costs than the United States for several drugs, is not a component of the market basket for reference pricing by many other countries. For this reason, domestic drug prices in Norway have not had much of a spillover effect into the rest of the world. However, under the MFN model, Medicare appears poised to adopt, outright, the Norwegian price for some drugs, which could then spill over into the

Japanese healthcare system where the national insurance plan includes the United States as one member of a small ERP market basket.

Key Takeaway: Manufacturers will benefit from coordinating market entry plans globally before beginning market entry price negotiations in any single nation.

The MFN model will start with 50 drugs, as shown above, and additional drugs may be added. There also is an expectation that once a drug is added, it is unlikely to be removed. Reasons for removal would include code retirement or withdrawal of a product from the US market. Among the 50 drugs selected for inclusion, almost all are available in other markets with some market data available. As a result, the chief priority for the makers of most drugs already included in the MFN pricing schema will likely be to minimize harmful rate reductions, which goal will be achieved only if the MFN price is stable. This effort will require not only considering pricing strategy within the current MFN nation, but also monitoring price trends and legal requirements for price reductions over time in other MFN model basket countries that could supplant the current MFN for a particular drug.

Drugs that are not in the top 50 list presently—but which have shown a significant increase in growth such that they may be in the top 50 drugs in net Medicare expenditures within the next few years—may be of immediate importance for manufacturer attention for potential MFN ratesetting.

For novel drugs, drug companies have the ability to plan a global market entry strategy informed by the MFN model's rules and drug pricing rules in the countries included in the MFN model basket. For example, a drug maker may choose to delay the entry of a drug into some OECD markets until after a US price has been established. Because ratesetting for Part B drugs under the MFN model is capped by the ASP, international prices cannot raise the US drug prices—they can only reduce them.

Key Takeaway: Pharmaceutical makers should begin planning for an ERP system in the United States regardless of what the future holds for the MFN model.

The MFN model is one of several ERP policies for drug payment under Medicare. As such, even if the MFN model is not implemented as published due to political or legal reasons, the probability is high that a model comprising an ERP in some form will be adopted. The MFN model will drive prices going forward based on price agreements set prior to such a model even being proposed. Alternative ERP policies, if implemented, are also likely to adopt prices negotiated in the ERP basket countries prior to the announcement of the ERP policy. Pharmaceutical companies that

are proactive in their ERP management strategies will have more control over their products' prices than companies that react to finalized policies.

Key Takeaway: OECD countries may need to reassess their drug price expectations.

Negotiations for drug prices in many countries have generally remained focused on the marginal costs and revenues of supplying the drug in that country. However, in a regime in which the negotiated price in one country may directly affect the price in another country with a large market (e.g., the United States), negotiations may need to consider the spillover effects of a price, which may be expected to result in higher prices in potential reference markets in order to make commercialization of drugs economically viable. Countries in the MFN market basket may wish to pay particular attention to pricing of drugs likely to be included in the MFN list, as these are the drugs for which pharmaceutical manufacturers may find that they have less ability to offer the drug at a lower cost while maintaining economic viability.

CONCLUSION

Any effort by pharmaceutical manufacturers to manage potentially negative financial impacts of the MFN model will likely be guided by a global market access plan that coordinates market-access divisions and plans an organized market-access strategy around the world. To be effective, the market-access plan must examine price expectations in countries in which market entry is planned, along with an analysis of existing and potential spillover effects, including those brought on by the MFN model in the US. This plan will likely include consideration as to whether or not it is economically viable to enter some markets. For manufacturers of drugs that are included or are likely to be included in the MFN model, plans regarding both pricing and anticipated sales volumes that are not coordinated across continents may result in negative financial impacts to the parent entity.

The MFN model is important not only as a specific policy, but also as a bellwether of the national conversation on pharmaceutical pricing. External reference pricing is just one approach to lowering domestic drug expenditures, and the MFN model, if implemented as published, will be a seven-year experiment with ERP. Whether or not this experiment achieves its goals, the larger question of how to manage pharmaceutical expenditures while promoting innovation and competition in the pharmaceutical industry will remain

The McDermott Difference

Companies with limited international market access experience may benefit from consultation with firms such as McDermott+Consulting and McDermott Will & Emery that have international reach and experience with pricing systems in multiple OECD nations, including the United States. Such consultation can help companies gain a better sense of the probability of the inclusion of their products in the MFN model and to plan realistic pricing expectations across nations before entering the market of any single nation.

McDermott Will & Emery

McDermott+ Consulting

FOR MORE INFORMATION, CONTACT

US CONTACTS

EMILY COOK
PARTNER
MCDERMOTT WILL & EMERY

ecook@mwe.com
Tel + 1 310 284 6113

PAUL GERRARD, M.D.
VICE PRESIDENT |
MCDERMOTT+CONSULTING

Pgerrard@mcdermottplus.com
Tel + 1 202 756 8802

DEBORAH GODES
SENIOR DIRECTOR |
MCDERMOTT+CONSULTING

dgodes@mcdermottplus.com
Tel +1 202 204 1455

PAUL RADENSKY, M.D.
PARTNER
MCDERMOTT WILL & EMERY

pradensky@mwe.com
Tel +1 202 756 8794

JESSICA ROTH
SENIOR DIRECTOR |
MCDERMOTT+CONSULTING

jmroth@mcdermottplus.com
Tel +1 202 204 1452

CHRISTINE SONG
SENIOR DIRECTOR |
MCDERMOTT+CONSULTING

csong@mcdermottplus.com
Tel +1 202 204 1453

RACHEL STAUFFER
DIRECTOR |
MCDERMOTT+CONSULTING

rstauffer@mcdermottplus.com
Tel +1 202 204 1460

KATIE WALDO
DIRECTOR |
MCDERMOTT+CONSULTING

Kwaldo@mcdermottplus.com
Tel +1 212 547 5433

RODNEY WHITLOCK
VICE PRESIDENT |
MCDERMOTT+CONSULTING

rwhitlock@mcdermottplus.com
Tel +1 202 204 1468

ERIC ZIMMERMAN
PARTNER
MCDERMOTT WILL & EMERY

ezimmerman@mwe.com
Tel +1 202 756 8148

McDermott Will & Emery

McDermott+ Consulting

EUROPEAN CONTACTS

SHARON LAMB
PARTNER
MCDERMOTT WILL & EMERY

slamb@mwe.com
Tel + 44 20 75776943

STEPHAN RAU
PARTNER
MCDERMOTT WILL & EMERY

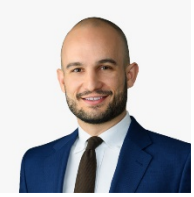
srau@mwe.com
Tel + 49 89 12712320

EMMANUELLE TROMBE
PARTNER
MCDERMOTT WILL & EMERY

etrombe@mwe.com
Tel + 33 1 81691535

JANA GRIEB
COUNSEL
MCDERMOTT WILL & EMERY

jgrieb@mwe.com
Tel + 49 89 12712323



DENIZ TSCHAMMLER
COUNSEL
MCDERMOTT WILL & EMERY

dtschammler@mwe.com
Tel + 49 89 12712335

MARION ABECASSIS
ASSOCIATE
MCDERMOTT WILL & EMERY

mabecassis@mwe.com
Tel + 33 1 81691478

McDermott Will & Emery

McDermott+ Consulting

OFFICE LOCATIONS

ATLANTA
1372 Peachtree Street
Atlanta, GA 30309
USA
Tel +1 404 260 8535
Fax +1 404 393 5260

BOSTON
28 State Street
Boston, MA 02109-1775
USA
Tel +1 617 535 4000
Fax +1 617 535 3800

BRUSSELS
Avenue des Nerviens 9 - 31
1040 Brussels
Belgium
Tel +32 2 230 50 59
Fax +32 2 230 57 13

CHICAGO
444 West Lake Street
Chicago, IL 60606-0029
USA
Tel +1 312 372 2000
Fax +1 312 984 7700

DALLAS
2501 North Harwood Street
Suite 1900
Dallas, TX 75201-1664
USA
Tel +1 214 295 8000
Fax +1 972 232 3098

DÜSSELDORF
Stadttor 1
40219 Düsseldorf
Germany
Tel +49 211 30211 0
Fax +49 211 30211 555

FRANKFURT
Oberlindau 54-56,
60323 Frankfurt a. M.
Deutschland
Tel +49 69 951145 0
Fax +49 69 271599 633

HOUSTON
Two Allen Center
1200 Smith Street
Suite 1600
Houston, TX 77002-4403
USA
Tel +1 713 653 1700
Fax +1 972 232 3098

LONDON
110 Bishopsgate
London
EC2N 4AY
Tel +44 20 7577 6900
Fax +44 20 7577 6950

LOS ANGELES
2049 Century Park East
Suite 3200
Los Angeles, CA 90067-3206
USA
Tel +1 310 277 4110
Fax +1 310 277 4730

MIAMI
333 SE 2nd Avenue
Suite 4500
Miami, FL 33131-2184
USA
Tel +1 305 358 3500
Fax +1 305 347 6500

MILAN
Via Dante 15
20123 Milan
Italy
Tel +39 02 36575701
Fax +39 02 36575757

MUNICH
Nymphenburger Str. 3
80335 Munich
Germany
Tel +49 89 12712 0
Fax +49 89 12712 111

NEW YORK
340 Madison Avenue
New York, NY 10173-1922
USA
Tel +1 212 547 5400
Fax +1 212 547 5444

ORANGE COUNTY
18565 Jamboree Road
Suite 250
Irvine, CA 92612-2532
USA
Tel +1 949 851 0633
Fax +1 949 851 9348

PARIS
23 rue de l'Université
75007 Paris
France
Tel +33 1 81 69 15 00
Fax +33 1 81 69 15 15

SAN FRANCISCO
415 Mission Street
Suite 5600
San Francisco, CA 94105-2533
USA
Tel +1 628 218 3800
Fax +1 628 218 3900

SILICON VALLEY
275 Middlefield Road
Suite 100
Menlo Park, CA 94025-4004
USA
Tel +1 650 815 7400
Fax +1 650 815 7401

WASHINGTON, DC
The McDermott Building
500 North Capitol Street,
NW Washington, DC 20001-1531
USA
Tel +1 202 756 8000
Fax +1 202 756 808

WILMINGTON
1007 North Orange Street
10th Floor
Wilmington, DE 19801
USA
Tel +1 202 756 8950
Fax +1 202 756 8087

McDermott
Will & Emery

mwe.com |