



**JOINT
LEARNING
NETWORK**
For Universal Health Coverage

Negotiated Solutions for Purchasing High-Cost Medicines

A Practitioner's Guide



WORLD BANK GROUP
Health, Nutrition & Population

© 2022 The International Bank for Reconstruction and Development / The World Bank
1818 H Street, NW Washington, DC 20433

www.worldbank.org

All rights reserved.

This volume is a product of the staff of the International Bank for Reconstruction and Development / The World Bank. The findings, interpretations, and conclusions expressed in this volume do not necessarily reflect the views of the Executive Directors of The World Bank or the governments they represent.

The World Bank does not guarantee the accuracy of the data included in this work. The boundaries, colors, denominations, and other information shown on any map in this work do not imply any judgment on the part of The World Bank concerning the legal status of any territory or the endorsement or acceptance of such boundaries.

Rights and Permissions

The material in this work is subject to copyright. Because The World Bank encourages the dissemination of its knowledge, this work may be reproduced, in whole or in part, for noncommercial purposes as long as full attribution to this work is given.

Any queries on rights and licenses, including subsidiary rights, should be addressed to the Office of the Publisher, The World Bank, 1818 H Street NW, Washington, DC 20433, USA; fax: 202-522-2422; e-mail: pubrights@worldbank.org.

Negotiated Solutions for Purchasing High-Cost Medicines

A Practitioner's Guide

Contents

ACKNOWLEDGEMENTS	5
ABOUT THIS DOCUMENT	6
Chapter 1. Negotiating Basics	8
What Are Managed Entry Agreements (MEAs)?	8
Types of MEAs	9
Advantages and Disadvantages of MEAs	13
Country Insights and Experiences with Negotiations	14
Summary of Main Conclusions	15
Chapter 2. Preparing for Negotiations	16
Making the Case for Preparation—Why Is Preparation Important in Negotiations?	16
Negotiation Preparation, Understanding the Industry Perspective: Key Insights into International and Intracountry Differential Pricing Principles	17
Negotiation Preparation Checklist: Six Organizational Steps	19
Summary of Main Conclusions	22
Chapter 3. Managing Negotiations and Long-Term Relationship Management	23
Useful Strategies to Adopt during Negotiations	23
Long-Term Relationship-Building and Management	26
Summary of Main Conclusions	27
Conclusion	28

Acknowledgements

This Guide was a collaborative effort undertaken by the World Bank Group's Health, Nutrition and Population (HNP) Private Sector Global Solutions Group (GSG) with the Joint Learning Network on Universal Health Coverage (JLN). The product was authored by Kathryn Boateng (World Bank) under the leadership of Andreas Seiter (World Bank) with significant contributions from other World Bank staff, namely Somil Nagpal, Ana Mercado, and Martin Mpungu Lutalo.

Special thanks go to the country contributors (detailed below) who participated in the JLN's learning exchange on Negotiated Solutions for Purchasing of High-Cost Medicines. Their openness, experience, and feedback provided the foundation for this collaborative's success. Further thanks go to our technical facilitators and expert consultants, including Damian Walker, Luka Voncina, Jaime Espin, and Jens Grueger whose expertise and specialist knowledge guided the series of workshops, as well as supported the final drafting of this output.

Finally, heartfelt thanks to the JLN Network Management team at Management Sciences for Health, Kamiar Khajavi, Sara Wilhelmsen, Maeve Conlin, Julie Lan Anh Hoang, Ana Amaris Caruso, and Amelia Zhao. Your professionalism, timely inputs, mastery of virtual meeting facilitation, and involvement throughout the months of learning and coproduction were enormously valuable.

PARTICIPATING COUNTRIES

Bangladesh

Tanvir Ahmed
Md. Iqbal Hossain
Nipa Chowdhury

Ghana

Ruby A. Mensah Annan
Francis Asenso-Boadi
Yvonne Sedegah

Indonesia

Eka Yoshida Syofian
Daniel Novian Dharma Setia Budi
Pak Ahmad Ansyori

Kenya

Shadrack Meme
Allan Kyalo Wambua
James Kanyange

Liberia

Eugene F. Miller
Kpakama L. Kromah
Mortor L. Richards

Malaysia

Fatkhiah Khalil
Nur Sufiza Ahmad
Norma Yusuf
Dinash Aravind

Namibia

Bona Nghishekwa

The Philippines

Arthur Lanuza
Vanessa Jara Saulog-Obera
Anna Patricia Tiosejo
Jeffrey Castro
Alexander Rupert Lim
Queenie Romero
Rikki Mae Pajarillo

Vietnam

Nguyen Khanh Phoung
Viet Nguyen Tuan
Hien Le

About This Document

Across the globe, decision makers at all levels of the health care system agree that patients should be given rapid access to innovative medicines that target life-threatening diseases such as cancer, multiple sclerosis, and hepatitis C. Governments face increasing amounts of pressure to introduce new technologies because of shifting and evolving health challenges. According to recent reports, noncommunicable diseases (NCDs)—including cardiovascular disease, cancers, strokes, chronic respiratory infections, and diabetes—presently contribute to 70 percent of worldwide mortality.¹ Low- and lower-middle-income countries (LMICs) face a dual challenge of having substantial infectious disease burdens, coupled with the increasing NCD caseloads. Biopharmaceutical innovation creates opportunities to address these unmet medical needs, but this carries a hefty price tag. Moreover, there are often uncertainties about clinical effectiveness of new medicines and about the impact they will have on the medicines budget. How then does a government balance its mandate to increase patients’ access to promising therapies while limiting the impact of high prices and uncertainty on its already strained public health resources?

One possible solution to this challenge are managed entry agreements (MEAs). Also known as patient access schemes, these contractual agreements have a framework of sharing the uncertainty of patient outcomes and financial impact between the payer and the market authorization holder, to facilitate access to new high-cost medicines.² They also tend to be confidential in nature. Today, many developed countries use MEAs to accelerate access to important innovative medicines while protecting their budgets. The confidentiality of these agreements, however, means that the terms and the strategies used to achieve successful outcomes in these agreements are not widely known. With limited information on what works and what does not work in the implementation of MEAs, many LMICs must navigate the negotiation landscape in the dark. The goal of the Joint Learning Network (JLN) learning exchange on Negotiated Solutions for Purchasing of High-Cost Medicines, which was organized on the same topic, and by extension the goal of this Practitioner’s Guide, is to provide countries new to MEAs with an insider perspective. It is hoped that the contents of this Guide will lift the veil on the nature of these negotiations and equip countries with the strategies and know-how they need, to successfully negotiate similar agreements.

Who Is This Guide for and How Is It to Be Used?

The target audience for this Guide is government officials from the Ministry of Health (MoH) and National Health Insurance Agencies, along with country representatives in LMICs who are either beginning their negotiation journeys or are currently engaged in negotiations in their respective countries. The Guide is geared toward those who are seeking to prepare and engage more appropriately with research and development (R&D) pharmaceutical companies in determining a mutually, win-win outcome in their own countries. The Guide features insights and experiences from medicines pricing experts, negotiating practitioners, country participants, and World Bank specialists. The countries that participated in the

-
- 1 “Sharing Knowledge on Innovative Medicines for NCDs: A Compendium of Good Practices for Sustainable Access,” November 21, 2018. <https://thedocs.worldbank.org/en/doc/792561542818915277-0090022018/original/MSHRTIGLOHICompendiumFinalVersion2Nov212018.pdf>.
 - 2 Syed Hasan, Christine Lu, and Zaheer-Du-Din Babar. 2018. “Access to High-Cost Medicines: An Overview.” 10.1016/B978-0-12-811945-7.00001-4. https://www.researchgate.net/publication/323556807_Access_to_High_Cost_Medicines_An_Overview.

exchange included Bangladesh, Ghana, Kenya, Indonesia, Malaysia, Namibia, the Philippines, and Vietnam with participants ranging from MoH pharmacists to hospital directors. The Guide recognizes that each country situation is different and does not take a one-size fits all approach. There are contextual differences (e.g., health financing arrangements, legal and policy frameworks, etc.) that must be considered when determining the appropriate negotiation strategy and terms of agreement.

What Is the Scope of This Guide?

This Practitioner's Guide is limited in scope to the country experiences, discussions, and presentations shared during the JLN learning exchange. The Guide does not quote the vast body of formative literature on drug price negotiations, reference pricing, and sustainable access strategies; it does, where appropriate, provide some additional information beyond the workshop for the purpose of context and added clarification. As the intention is to provide negotiating practitioners with an easy-to-use, quick reference guide, simple and clear language has been used to make it easier to apply and adapt the presented information.

How Is This Guide Structured?

The Guide is organized around the learning exchange's three sessions and discussions. It starts off by introducing stakeholders to the basics of negotiation, terminologies, and the range of negotiated agreements available. Next, it outlines how countries can prepare for these negotiations and then discusses how to manage the actual negotiations, while keeping the long-term relationship in mind. Here is a quick overview:

- 1. Chapter 1: Negotiating Basics** – This initial chapter introduces the reader to managed entry agreements (MEAs); it covers why countries negotiate; the different types of negotiated agreements, the advantages and disadvantages of negotiated agreements; and it clarifies ambiguities around terminologies.
- 2. Chapter 2: Preparing for Negotiations** – This chapter covers how countries can prepare for negotiations with industry. It provides insights into the manufacturer's perspective and includes a negotiation preparation checklist.
- 3. Chapter 3: Managing Negotiations and Long-Term Relationship-Building** – This chapter focuses on how to manage the actual negotiation process. It discusses useful and not-so-useful strategies during the negotiation process. The chapter also dives into the importance of long-term relationship management to improve future outcomes.

In each chapter, the Guide zeros in on the essence of the expert presentations and ensuing discussions, to highlight the most useful tips or areas of interest. Where applicable, chapters may include a box on "Country Experiences" drawing out actual country examples from the discussion and/or "Quick Tips" that are helpful for navigating the negotiating process.

What Does This Guide Do?

This Practitioner's Guide is a compilation of key information and discussion takeaways from the JLN's Negotiated Solutions for Purchasing High-Cost Medicines Country Learning Exchange, held virtually between October 2021 and January 2022. The learning exchange comprised four sessions. Over 30 participants from eight countries were introduced to negotiated solutions from different perspectives. This Practitioner's Guide is the output of the learning exchange. It draws out the main learning, discussions, and takeaways from the sessions, and synthesizes the information into practical tips and approaches to help countries lead successful negotiations with manufacturers.

Chapter 1.

Negotiating Basics

Managed Entry agreements—What Are They?

Let's begin by talking about managed entry agreements (MEAs): What are they and how might we define them? Generally, MEAs are formal arrangements between payers and pharmaceutical companies that seek to share risk with respect to the introduction of new health technologies. One definition by Carlson et. al (2010) put it this way: "A Managed Entry Agreement is an arrangement between a manufacturer and payer/provider that enables [patients'] access to (coverage/reimbursement of) a health technology subject to specified conditions. These arrangements can use a variety of mechanisms to address uncertainty about

the performance of technologies or to manage the adoption of technologies in order to maximize their effective use or limit their budget impact."¹ Thus, MEAs typically involve an agreement between two main players: the **payer** (either a government, public fund holder, or a private holder of pooled resources such as an insurer) and a **pharmaceutical company** that manufactures and markets a drug. MEAs are known under a variety of names, including risk sharing, coverage with evidence development (CED), access with evidence development (AED), payment for outcomes, and performance-based reimbursement schemes.

Why might countries need MEAs? Countries face pressure to introduce innovative technologies to tackle challenging health system needs but under very limited budget conditions. To overcome this tension between funding new but expensive technologies while obtaining value for money, coupled with the uncertainties of a new drug's clinical effectiveness, payers are increasingly adopting innovative reimbursement approaches to help mitigate the uncertainties. In most cases, manufacturers are willing to share the financial risk with payers since it allows them

→ **Managed Entry Agreement** is an arrangement between a manufacturer and payer/provider that enables patients' access to coverage/reimbursement of a health technology subject to specified conditions.



What do we mean by high-cost medicines? HCMs are medicines of high potential value to the health system that create a conflict for public payers between the goal of providing access for patients and available financial resources. Unlike generics, HCMs typically enjoy market exclusivity through patent protection.

1 J. J. Carlson, S. D. Sullivan, L. P. Garrison, P. J. Neumann, and D. L. Veenstra. 2010. "Linking Payment to Health Outcomes: A Taxonomy and Examination of Performance-Based Reimbursement Schemes between Healthcare Payers and Manufacturers." *Health Policy* 96: 179–90. <https://pubmed.ncbi.nlm.nih.gov/20226559/>.

to bring their product to the market. In some cases, it also helps them to meet their corporate social responsibility goals and professed commitment to increase access to high-cost medicines (HCMs) in LMICs. MEAs are used for innovative HCMs, in lieu of traditional procurement and pricing strategies, because these drugs typically benefit from a legal monopoly (patent), which allows manufacturers to charge high prices. Traditional methods, such as tenders, still play a role if there are several therapeutically equivalent products of the same category on the market. This has been the case, for example, for hepatitis C antivirals.

Risk-sharing or reimbursement schemes such as MEAs are different from Health Technology Assessment (HTA)—see explanation (Box 1).² Over the last 10 years, HTA has become an increasingly important part of the national decision-making process for acquiring HCMs. The evidence provided by HTA helps payers to make decisions on the selection and utilization of health technologies (including emerging new technologies), to promote efficient and appropriate health resource allocation, while maximizing value for patients and the health care system.³ HTA helps decide which products the payer should enter into MEA negotiations for and informs the terms of the MEA.

Box 1. Health Technology Assessment 101

A simple yet insightful definition of technology assessment is “the systematic study of the effects on society, that may occur when a technology is introduced, extended, or modified, with emphasis on the impacts that are unintended, indirect, or delayed” (Coates 1976). In the health context, technology assessments provide a bridge between research and clinical decision-making (including expenditure on medicines). HTAs and MEAs are not interchangeable—they work in tandem to help decide which medicines should be reimbursed and under what conditions.

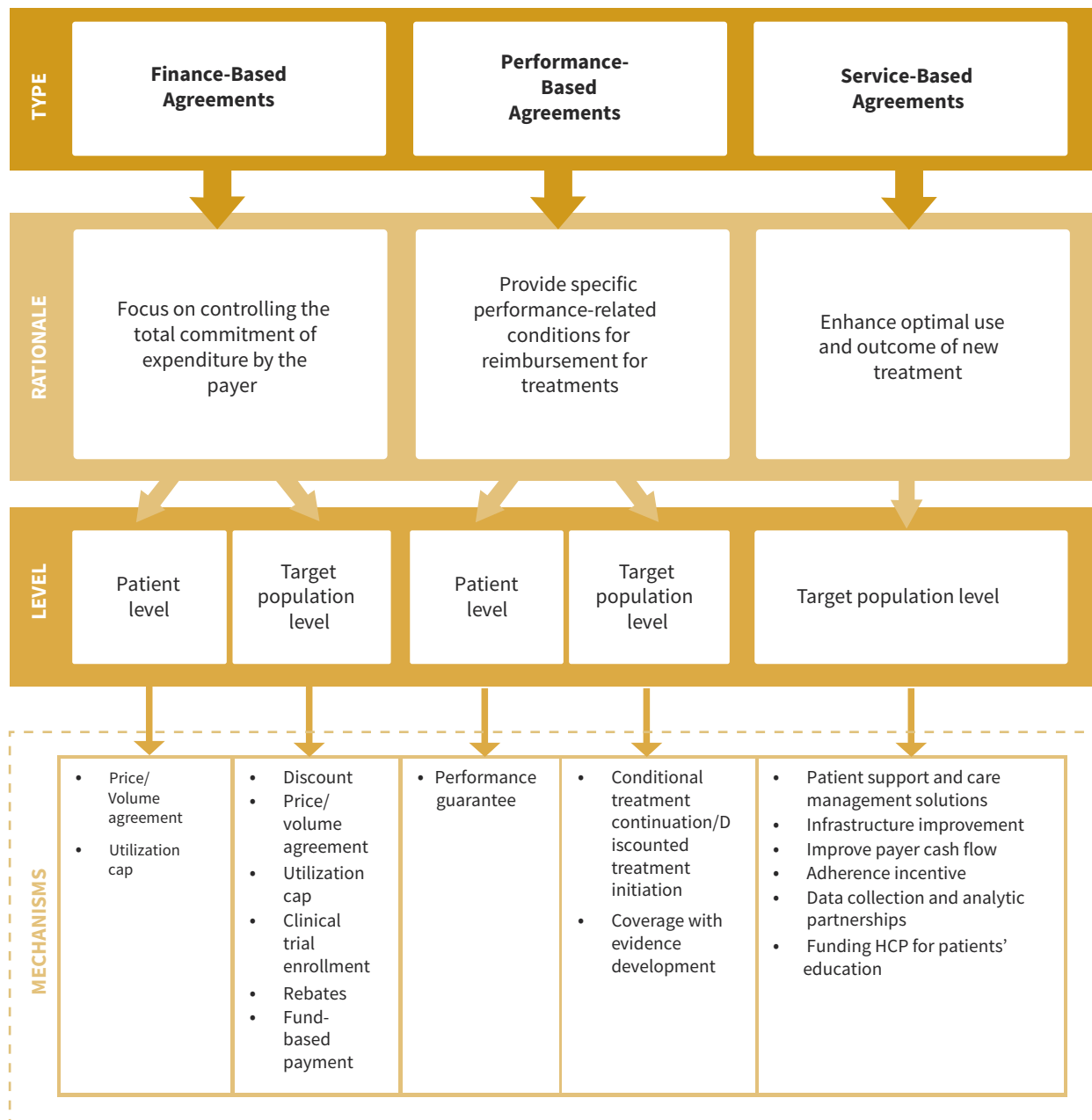
Source: Coates J.F. 1976. Technology assessment-A toolkit. Chetech. 1976;372-83

Types of MEAs

MEAs generally fall into three categories. The following diagram⁴ highlights the core characteristics of each type of agreement and the rationale behind each.

-
- 2 Adapted from the expert presentation on “Managed Entry Agreements” delivered during the JLN’s learning exchange, October 14, 2021.
 - 3 Yingyao Chen. 2022. “Health Technology Assessment and Economic Evaluation: Is It Applicable for the Traditional Medicine?” *Integrative Medicine Research* 11, no. 1 (March). <https://www.sciencedirect.com/science/article/pii/S2213422021000433#>.
 - 4 M. Dabbous, L. Chachoua, A. Caban, and M. Toumi. 2020. “Managed Entry Agreements: Policy Analysis from the European Perspective.” *Value Health* 23, no. 4 (April): 425–33. [https://www.valueinhealthjournal.com/article/S1098-3015\(20\)30041-3/fulltext](https://www.valueinhealthjournal.com/article/S1098-3015(20)30041-3/fulltext).

Flow Diagram 1: Classification of Managed Entry Agreements



Source: M. Dabbous, L. Chachoua, A. Caban, and M. Toumi. 2020. "Managed Entry Agreements: Policy Analysis from the European Perspective." *Value Health* 23, no. 4 (April): 425–33. [https://www.valueinhealthjournal.com/article/S1098-3015\(20\)30041-3/fulltext](https://www.valueinhealthjournal.com/article/S1098-3015(20)30041-3/fulltext).

Note: HCP = Healthcare provider.

Finance-based agreements are the most common type of MEAs used in countries. They tend to address payer concerns regarding the drug's budget impact on the patient and/or health system, by reducing the net price of the product. These arrangements apply instruments such as discounts, price/volume agreements, utilization caps, clinical trial enrollment, rebates, and fund-based payments. Performance-based agreements, on the other hand, make payments to the pharmaceutical companies conditional on product performance. To deal with the uncertainty associated with the clinical outcomes of the drug among the target patient population, performance guarantees, conditional treatment continuation/discounted treatment initiation, and coverage with evidence development are some of the tools leveraged in performance-based agreements. Service-based agreements are aimed at managing utilization to optimize the use and outcome of new treatments on a target population. In these cases, patient support and care management solutions, infrastructure improvement, adherence incentives, data collection, and analytic partnerships are some of the instruments included in the agreements. Box 2 discusses MEAs and their application in the real world.

Box 2: Understanding How Different Forms of MEAs Play Out in Real-Life Contexts – A Discussion

In the current environment, pharmaceutical companies are aware that payers are hesitant to deal with risk. To convince payers that a new treatment is worth budgeting for, many pharmaceutical companies have shifted the weight of their resources to improving pricing strategies and payer collaborations, all to identify win-win scenarios that minimize risk for the payers. All forms of MEAs include some innovative element to deflect or limit the risk for the payer. For example, finance-based agreements (FBAs) tend to be the most common in real world settings because of their simplicity and predictability in the price-volume agreement. These schemes may have fixed payments to service a population independent of the exact volume of the drug used. For example, Company X gives countries access to its current (and any future) portfolio of treatments at a fixed price for a number of years. Another way FBAs can be structured is to have pre-agreed sales thresholds or per-unit use, which if exceeded, must be compensated for by the pharmaceutical companies. In this case, you could negotiate an agreement whereby the first 1,000 patients pay the price the company lists, with any subsequent patients getting the treatment for free. Many countries are drawn to FBAs not only to control the budget but also to ensure predictability. Performance-based agreements (PBAs) may be particularly well-suited for medicines that are expected to achieve measurable treatment outcomes in a limited time frame. PBAs build in a “safety net” into the agreement for the payer in case a drug does not achieve its stated primary outcome. In these cases, drug cost is (partly or in full) refunded when certain success criteria are not met (treatment response, event free, etc.) For example, Company Y refunds part of the cost of its therapy for a blood disorder when patients require transfusions, despite treatment. PBAs are more in line with a value-for-money proposition, but harder to monitor, and require reliable data to measure performance. Under service-based agreements (SBAs), manufacturers provide patients with additional services to ensure optimal medical treatment. These services may be support programs, educational programs, or home care visits by qualified nurses, to name a few. These schemes can also provide data demonstrating cost-effectiveness, as well as patient outcomes in the real care setting (real-world data), both of which are important to payers. An actual real-life example of an SBA is Company Z offering a discount on its cancer drug in LMICs (e.g., the Philippines) after empty vials were returned.

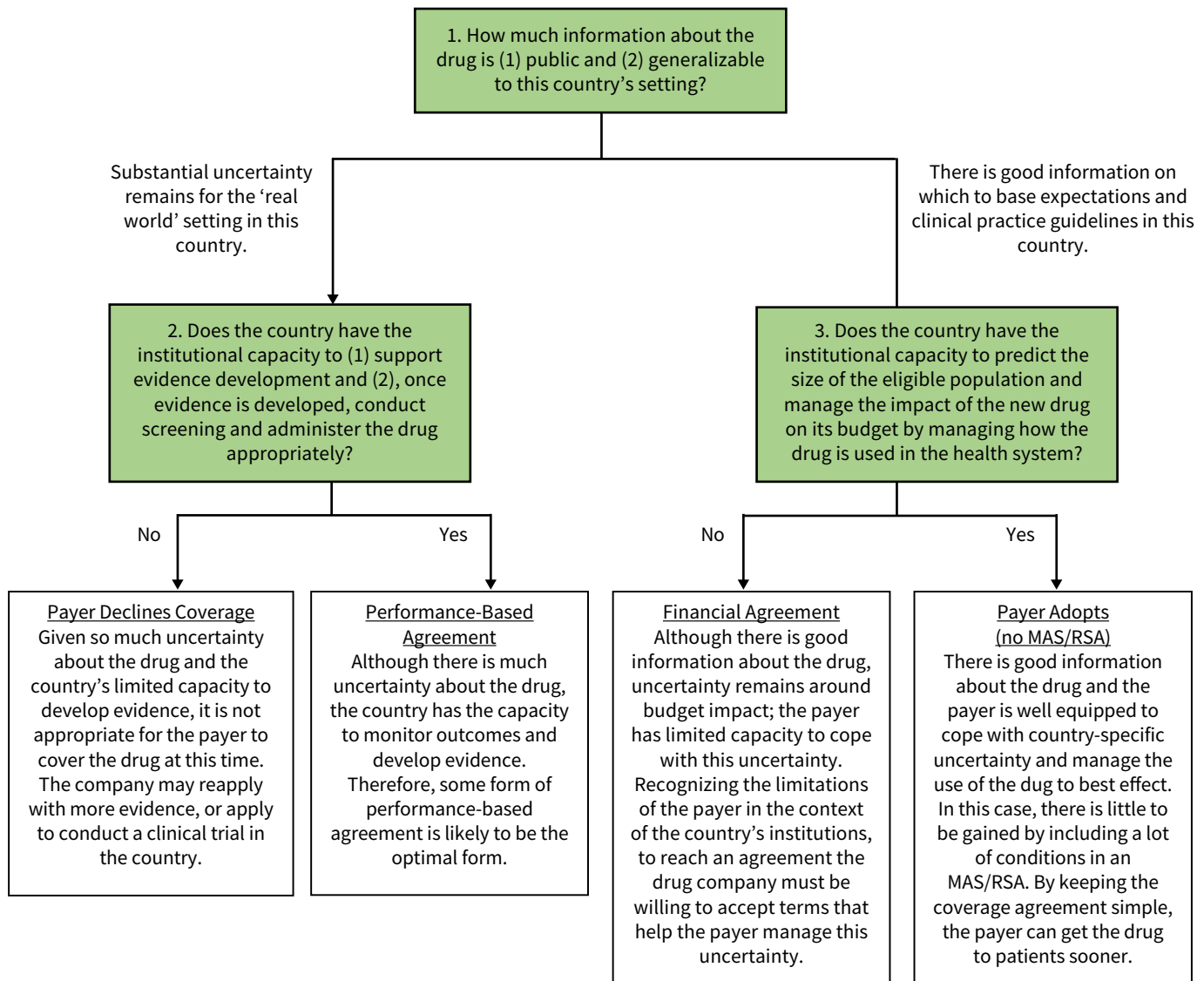
Q: How do you determine which type of agreement is best for your health care system?

A: MEAs work best when they are tailored to the specific country context in which they are being used. Begin by carefully considering the characteristics of the therapy to be reimbursed and the characteristics of the health care payment system in your country. If it's a price/affordability issue, consider an FBA. If treatment success can be relatively easily documented, perhaps a PBA is the right option. If the answer isn't as clear-cut—given that several factors beyond price (e.g., usage, payment structure, type of therapy under evaluation, characteristics of your health care system, etc.) drive the deliberative process—consider a hybrid model that combines aspects of financial, performance-based, or service-based agreements. Combining agreements to construct a reimbursement mechanism most suited for your country's preferences is always acceptable. Also, remember that MEAs should not only be about bringing in new drugs into the country. Consider other ways the health system could benefit from the introduction of the new drug and build that into your negotiated agreement. Some of these improvements could be disease-awareness programs, early detection screening initiatives, improving diagnostic facilities, establishing centers of excellence, training specialists, developing a national registry of the disease to better understand the disease burden, and working to establish national treatment guidelines.

Source: Adapted from the expert presentation on “Managed Entry Agreements” delivered during the JLN's learning exchange, October 14, 2021

Additionally, this decision tree model is a helpful tool to use when thinking through your decision on which type of MEA to adopt, if at all.

Flow Diagram 2: Simplified Decision Tree Framework to Determine Optimal Type of MEA-



Source: Adapted from "Sharing Knowledge on Innovative Medicines for NCDs: A Compendium of Good Practices for Sustainable Access," November 21, 2018. <https://thedocs.worldbank.org/en/doc/792561542818915277-0090022018/original/MSHRTIGLOHICompendiumFinalVersion2Nov212018.pdf>.

Notes: MAS = Managed Access Strategy; RSA = Risk-Sharing Agreement.

Advantages and Disadvantages of MEAs

MEAs can provide multiple benefits to providers/payers seeking to improve access to innovative medicines. While the linkage between reimbursement and a technology's actual performance, utilization, and budget impact in these agreements may seem attractive, there are several risks to keep in mind when deciding to pursue an MEA (see Table 1 below).

Table 1: Advantages and Disadvantages of MEAs from the Provider/Payer Perspective

Advantages	Disadvantages
Provide earlier access of promising technologies to patients.	High transaction costs for both parties. In the payer's case, the challenge relates to the burden it places on the health system, in terms of administration, cost, and the need for data collection and analysis.
Share risk with manufacturer if product not performing as agreed.	Needs an agreed methodology to define and verify performance.
Limit total budget impact.	Risk that the product does not show expected clinical benefit (but risk is now shared).
Build evidence base to resolve uncertainties.	Possible withdrawal of a technology at the end of the agreement/difficult to withdraw once in practice.
Investment in innovation is promoted.	Need for agreements to be renegotiated periodically.

Source: Adapted from expert presentation on "Managed Entry Agreements" delivered during the JLN learning exchange, October 14, 2021.

The greatest concern for MEAs is the high administrative burden they place on the health system. This problem may be particularly true for PBAs, which require patient monitoring and data collection to verify whether the stipulated conditions have been met. Additionally, all MEAs have to be renegotiated periodically, ideally every four years or less to accommodate new evidence on the drug's clinical effectiveness. MEAs also require enabling legal and policy frameworks, which may be absent in LMIC contexts, where limited knowledge of MEAs by relevant stakeholders make it unlikely for these arrangements to be considered as a policy tool.



Quick Tip #1

Always consider your health system's capacity to manage MEAs; weigh the benefits and risks associated with MEAs, compared with other more traditional reimbursement/access strategies.

Country Insights and Experiences

A study on MEAs by Castro et al. (2018) looked at 285 agreements worldwide. It found that the majority of MEAs (close to 68 percent) are located in Europe. The study did not find significant numbers of MEAs in LMICs, where it's possible such agreements exist but are happening under different names and/or do not quite fit the mold of traditional MEAs. Country participants during the JLN learning exchange confirmed this finding, sharing that they use special pricing arrangements or other strategies to influence prices of medicines financed by the public sector. These arrangements, which are discussed in detail in Box 3, range from traditional reimbursement approaches (Bangladesh), memoranda of understanding with pharmaceutical companies (Ghana), to pooled procurement/third party contracting through nongovernmental/faith-based organizations (Kenya).

Box 3: Sharing Actual Country Examples with Patient Access/Reimbursement Schemes from the JLN Learning Exchange

- **The Philippines - Traditional Reimbursement Approach**

In the Philippines, the health sector (PhilHealth) has partnered with pharmaceutical companies to deliver their “Z Benefit Package.” In 2012, the Philippines introduced a special benefit package to address health conditions that trigger prolonged hospitalization and very expensive treatments. Initially, the cases identified under the “Z Benefit” were childhood acute lymphocytic leukemia (ALL), breast cancer, and prostate cancer. PhilHealth pays for the whole treatment of the disease from diagnosis to maintenance. To make the package affordable, PhilHealth negotiates with pharmaceutical companies for the lowest price on a yearly basis.



- **Ghana - Memorandum of Understanding (MOU)**

In Ghana, MOUs are common when it comes to negotiating prices of HCMs with pharmaceutical companies. For example, in 2019, Ghana signed a five-year MOU with a manufacturer to make hydroxyurea, a sickle cell medicine available in Ghana. The goal was to improve the diagnosis and to speed up the pace of treatment for people with sickle cell disease. The National Health Insurance Authority (NHIA) conducts the negotiations with the pharmaceutical companies and presents their final recommendations to the Ministry of Health for approval.



- **Kenya - Pooled Procurement Models**

In Kenya, faith-based organizations (FBOs) play a vital role in ensuring access to essential medicines and in the delivery of health services to patients. The Mission for Essential Drugs and Supplies (MEDS)—a partnership of the Kenya Conference of Catholic Bishops (KCCB) and Christian Health Association of Kenya (CHAK)—engages in pooled procurement models with other regional FBOs. These FBOs act as a single purchasing block to purchase health commodities for their target population (usually those with lower incomes), and therefore benefit from improved economies of scale. The intervention helps to make medicines available at affordable prices and to enhance access.



Source: Adapted from discussion with participants during the JLN learning exchange on Negotiated Solutions for Purchasing High-Cost Medicines, October 2021- January 2022.

So, do these special pricing arrangements qualify as MEAs? For any arrangement to qualify as an MEA, it needs to be legally binding on both parties. If this is not the case, then it cannot be enforced. MEAs should take the form of a formal written contract, clearly identifying the rationale for the agreement, aspects to be assessed, methods of review, and the criteria for ending the agreement. The agreement needs to be between a manufacturer and a payer with a means to track administrative data so penalties or bonuses can be enforced. Standard pooled procurement models do not meet the criteria for MEAs but have a role to play in ensuring access to affordable generic medicines.

Summary of Chapter 1

- MEAs can increase patient access and be useful to manage technology diffusion and optimize use.
- MEAs can be used when HTA identifies concerns about key outcomes, or when costs or budget impacts are material to a reimbursement decision.
- If the technology does not perform to pre-agreed expectation, utilization, or budget impact, both parties share the risk.
- MEAs are administratively complex and not easy to negotiate; they come with advantages and disadvantages to consider before they can be implemented.
- LMICs have limited experience with MEAs and may not always have the necessary infrastructure in place to effectively apply different types of MEAs.
- Currently, LMICs use a variety of special pricing approaches—pooled procurement, traditional reimbursement, MOUs, and other alternative courses of action to procure HCMs.

Chapter 2. Preparing for Negotiations

Preparation is easy to ignore during the negotiating process, but it is the first step to ensure a successful outcome. Over 80 percent of the negotiation outcome is commonly achieved in the prenegotiation phase.⁵ While there are many approaches to successful negotiations, the best negotiations share three defining characteristics; they take the time to consider (i) the outcome they want, (ii) what the other party values, and (ii) the alternatives available to them. By embracing these fundamentals—through the six organizational steps provided in this chapter—countries can improve their odds in a negotiation.

” **Every battle is won or lost before it is ever fought**
- Sun Tzu

Making the Case for Why Preparation Is Important in Negotiations.

One commonly encountered problem in bargaining situations is **information asymmetry**. The bad news? Companies tend to be better informed and better prepared because of the time and resources they have dedicated to researching and developing their product. Companies tend to have more local resources (human and time) than public payers, who often need to negotiate with multiple companies on multiple products simultaneously. Additionally, companies have staff extensively trained in negotiations, along with support from key medical doctors and patient organizations. The good news? Information asymmetry can be decreased through diligent preparatory work. Negotiation training is available for payers as well. While innovative companies are monopolists, they may face a degree of competition from other products on the market treating the same conditions—payers could time negotiations such that they discuss competing products in parallel, giving them an advantage over the involved companies. As the payer, you also tend to be the only buyer in town and therefore can exert considerable control over the purchase price of a product.

⁵ Negotiation Preparation - Key to Success - <https://www.negotiate.org/negotiation-preparation-key-to-success/> (accessed December 1, 2021).

Negotiation Preparation, Understanding the Industry Perspective: Key Insights into International and Intracountry Differential Pricing Principles.

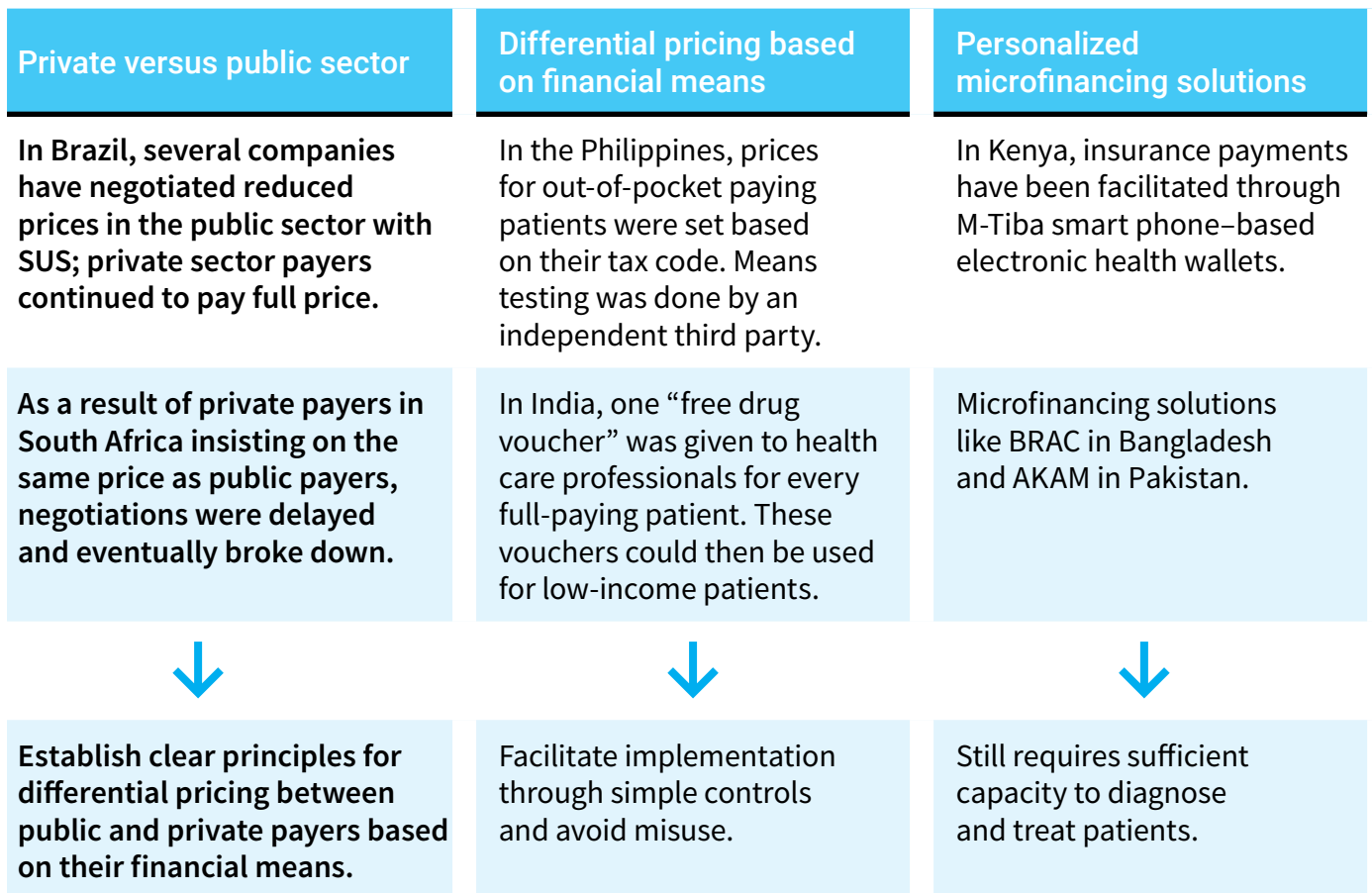
Finger-pointing over rising drug prices charged by pharmaceutical companies has been around for a long time. Over the last decade, however, a significant number of major pharmaceutical companies have moved away from profitability as the only goal, to adding access goals for their managers. These companies now have public commitments to creating access to their medicines. The underlying rationale behind this shift in priorities is two-fold: first, and as discussed in Chapter 1, the epidemiology of the world has changed significantly over the last decade with the rise of NCDs in LMICs. Companies are under pressure from their investors to report back on what they are doing to improve access to disadvantaged populations, from a corporate social responsibility perspective; second, commercial imperatives drive the decision making too—if a drug is being commercialized in only 20 percent of the world, the return on investment is limited. Thus, major pharmaceutical companies have promised to adopt **international differential pricing (IDP)** principles, which have prices typically anchored to gross domestic product (GDP)/per capita (with purchasing power parity [PPP] adjustment) to optimize the balance between access and price. For example, in 2013, Company Z used differential pricing to increase patient access to its cancer drugs by 50 percent in four years. At the time, there was limited availability of these drugs in many countries including China and Brazil. Through a variety of approaches (e.g., incremental price reduction, patient assistant programs, innovative subscription contracts, and direct price discounts), it successfully doubled access to the drugs in LMICs with a significant volume component, especially for China and Brazil.⁶

“**Over the past decade, major pharmaceutical companies have moved away from price to access**
- Jens Grueger, *medicines pricing and access expert.*

If a reference price exists for the drug you're negotiating, then factoring in IDP principles should give you, the payer, some initial indication of the price the pharmaceutical company is willing to accept for the drug in your country. In addition to IDP, “**intracountry differential pricing**” is an attractive option for pharmaceutical companies (see Figure 1).

Taken together, these perspectives help the payer understand the industry position, what approaches or arrangements currently exist in other LMICs, and what it might take to identify win-wins in your particular country's negotiations.

6 Expert Presentation delivered by Jens Grueger (Medicines Pricing and Access Expert) during JLN learning exchange, November 7, 2021.

Figure 1: Examples of Differential Pricing/Intracountry Differential Pricing from around the World

Source: Adapted from expert presentation delivered by Jens Grueger (Medicines Pricing and Access Expert) during the JLN learning exchange, November 7, 2021

Notes: SUS = Sistema Único da Saúde; BRAC = an international development organization headquartered in Bangladesh; AKAM = Akan Khan Agency for Microfinance.



Quick Tip #2

Remind pharmaceutical companies of their commitment to implement equitable and sustainable pricing solutions to expand access when negotiating with them.

Quick Tip #3

Collaborate with industry to address nonprice barriers to access to realize access/ volume expansion. Companies are willing to concede on price if they know that other access barriers have been removed and is leading to broader outreach of their medicines.

Quick Tip #4

Facilitate confidential solutions and global differential pricing principles to address industry concerns around price referencing.

Negotiation Preparation Checklist—Six Practical Organizational Steps

The negotiation process can seem daunting but having a to-do list of helpful steps and strategies can assist you in navigating it successfully. Here are some practical steps to get you started:

1. Carefully select your negotiation team – When you have been chosen by your government to lead a negotiation with a major pharmaceutical company, it is best to ensure that every member on your team is fully aligned with your position and has no conflict of interest to declare. A negotiation can be derailed because someone on the negotiation team has a conflict of interest and/or is going “off message” during the negotiation.

2. Assign roles – Negotiations for HCMs typically involve teams, because of the high stakes involved and the need to ensure transparency and integrity of the process. To build a good team, you need to select people who complement each other and who can challenge each other to think outside the box.⁷ In a negotiation, there are a few roles that are integral to any winning team. These roles include a leader who acts as the spokesperson at the negotiating table; a numbers/data person who tracks all the data during the negotiation and ensures that you are not worse off in the long term, even if short-term gains look good; an expert or specialist, who can offer an expert opinion when needed; and finally an observer—someone who does not actively take part in the negotiations, but observes the proceedings and gives feedback to the team.⁸ This person should not have any stake in the outcome of the negotiation. Adding a note taker and logistics person may also be helpful and allow the core team to stay focused on the content.

3. Do your homework – This is the crux of the preparation phase. Ensure that you have access to and have reviewed all the relevant international databases and information available to you. This includes international HTA documents from the United Kingdom’s National Institute for Health and Care Excellence (NICE),⁹ the Scottish Medicines Consortium (SMC),¹⁰ and the Transparency Committee (France).¹¹ Also, make a point to review data on clinical trials and information from experts and independent third parties (physicians, domestic organizations, and associations). Budget impact analyses and/or cost-effectiveness analyses can be particularly helpful in cases where resources are limited. You will also want to research the other party as thoroughly as possible to understand and prepare for its negotiating position. Feel free to reach out to the company with any questions or requests for information you may need and cross-check with experts. This may also give you some insights into what the company’s business objectives and preferred outcomes are. The added value of researching both sides helps you identify any possible trade-offs, determine your most desired and least desired outcome, and your “Plan B” or BATNA (best alternative to negotiated agreement).



Ensure that you have access to and have reviewed all the relevant international databases

- Luka Voncina, *drug negotiating expert, payer side.*

7 “The Power of Team Negotiations—How to Make Them Work?” file:///C:/Users/wb338730/OneDrive%20-%20WBG/Desktop/JLN%20Toolkit/The+Power+of+Team+Negotiations_3.pdf (accessed December 3, 2021).

8 “The Power of Team Negotiations—How to Make Them Work?” file:///C:/Users/wb338730/OneDrive%20-%20WBG/Desktop/JLN%20Toolkit/The+Power+of+Team+Negotiations_3.pdf (accessed December 3, 2021).

9 Available at <https://www.nice.org.uk/>.

10 Available at <https://www.scottishmedicines.org.uk/>.

11 Available at https://www.has-sante.fr/jcms/c_1729421/en/transparency-committee.

4. Discuss and define your goals – You are in the driver’s seat, and thus you define the context, process, and criteria for the negotiations. Begin by outlining what you are trying to achieve; identify how important the negotiation is for your health system. For example, are you negotiating something you absolutely need, that is, a unique medicine with life-saving potential? Or is it about a medicine with acceptable alternatives on the market? In either case, careful consideration of what is at stake will help with your goal-setting for the negotiation. Box 4 below highlights some further guiding questions to think about when preparing for the negotiation.

Box 4: Useful Questions for Preparing a Negotiation

- What are you negotiating: a product, a service, or an outcome?
- Is it a single product? Class of products? Portfolio of products?
- What are current prices of these technologies? In your and other countries with a similar income bracket?
- Are there treatment alternatives, and what are their comparative effectiveness?
- Are there issues beyond clinical effectiveness that are relevant for you?
- What are the financial implications (costs and savings) beyond price?
- What does the company want? Is its product facing competition from other innovative drugs? Patent timing? Are there aspects of the supplier that are relevant for you?
- Is it “just about this negotiation” or about a long-term relationship?

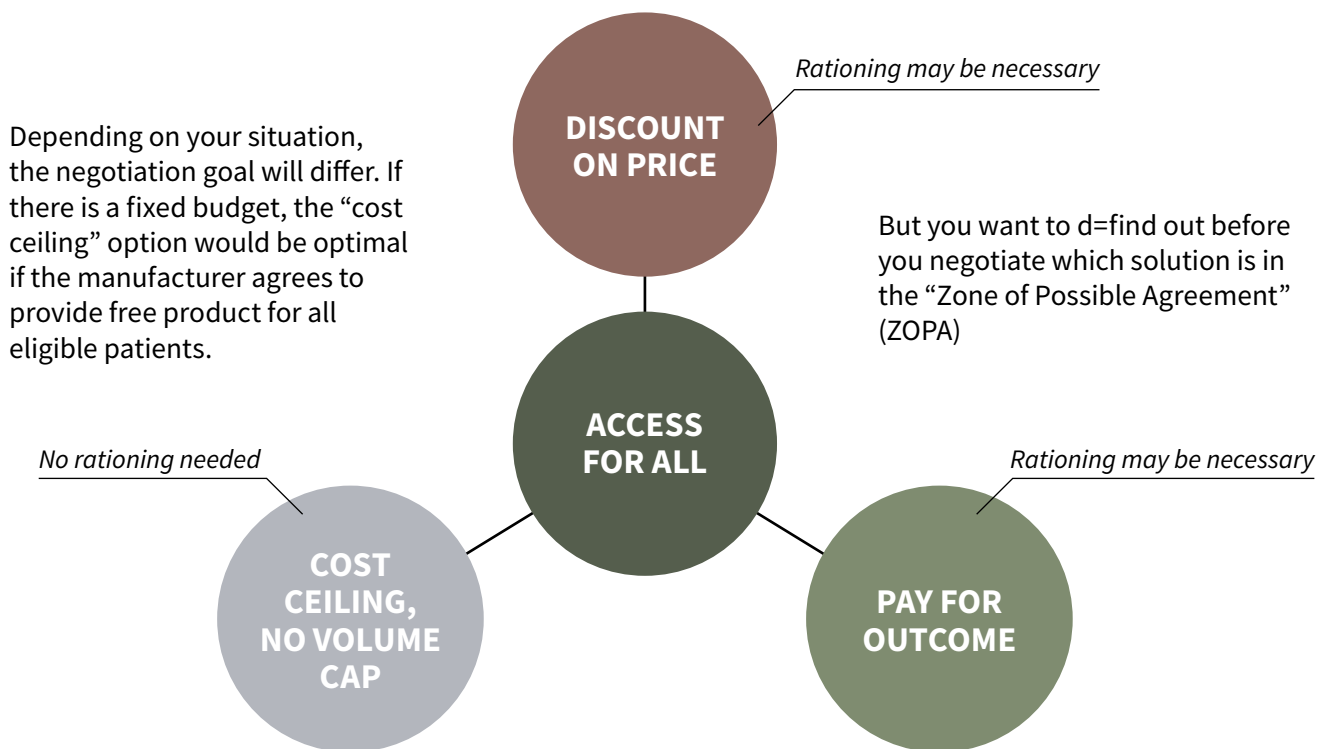
Source: Adapted from the expert presentations during the JLN learning exchange (October 2021–January 2022).

As the questions above have alluded to, also consider whether your government simply wants you to negotiate the lowest possible price for a drug, or if there are other benefits beyond price you could build into the agreement? Price should not be the only issue on the table. It is possible the other side would be willing to work with you in tangible ways to help strengthen your health system.¹² Depending on what their goals are, you can offer pharmaceutical companies access to crucial drug information data and/or participation in a stakeholder dialogue on health policy issues in exchange for these added benefits. In the end, you should aim for a win-win negotiation outcome where both parties walk away with an acceptable result.

Your country’s financial position in any given budgetary period should also be considered when determining which goal or outcome would be desirable. See Figure 2, which highlights an example of a country with a fixed budget, and the potential goals/outcomes for that negotiation.

¹² Within the limits of the IFPMA Code of Practice or a similar national framework, see https://www.ifpma.org/wp-content/uploads/2018/09/IFPMA_Code_of_Practice_2019.pdf.

Figure 2: Negotiation Goal-Setting—What to Consider in a Fixed Budget Situation?



Source: Adapted from presentation by Andreas Seiter given during a workshop on “Negotiating with Pharmaceutical Companies—An Introduction for Practitioners.”



Quick Tip #5

Have a comprehensive plan in mind! When negotiating, always keep a bird’s eye view of your country’s entire health needs and the corresponding budget availability for purchasing the needed medications. This will allow you to figure out where the company you are negotiating with, and the product being purchased, falls within the overall plan for your country for that budgetary period.

Once you have established your goal, it is now important to turn to what the other party’s goal might be. You not only need to have a clear understanding of your country’s objectives and preferred outcomes but should put yourself in the other party’s shoes to understand its business priorities, pressures, and objectives to determine the best approach to the negotiation. Based on the constraints industry faces, what is its opening position likely to be and how would you respond? What do you believe its must-haves, good-to-have, and BATNA will include? What tools can you leverage during the negotiation? For example, when you are negotiating drugs in a crowded disease category with multiple options, the calculus is different. In such cases, a new treatment will typically be priced similarly to the competitors, and you can use the prevailing competition as leverage to negotiate for a lower price. Understanding the industry perspective and current situation vis-à-vis other products is important to arriving at a good, negotiated outcome. Once you have a good grasp of both sides, then it’s time to set targets for your negotiation, including your most desired and least desired possible outcome, along with any possible trade-offs or concessions. Write out these goals using helpful statements such as, “If the company does (X), we will respond with (Y); and if the company does (A), we need to do (B),” etc., to help guide you.

5. Define rules and stages of negotiation in prediscussion with the negotiation partner – Set up a “get to know” meeting to establish the ground rules for the negotiation: determining where, when, with whom, and under what time constraints the negotiations will take place beforehand is important. During this premeeting, talk about who is taking notes and sharing minutes. This is also a good time to establish ground rules for information exchange prior to the negotiations. Use this opportunity to ask questions; to understand the other side’s organizational hierarchy, and whether you are dealing with local or global teams; and especially if the decision makers will be in the room. The value of taking time to get to know the other party and to build rapport before you negotiate cannot be overemphasized.

6. Prepare your BATNA – What happens if negotiations fail? What happens if you can’t reach an agreement? In cases where goals cannot be achieved, what is the “best alternative to a negotiated agreement” (BATNA)? It’s worth putting in the effort to outline a number of options before arriving at the negotiating table and taking steps to improve the BATNA. Overall, remember that there is a very important shared goal before both parties—providing patients with access to life-saving interventions. This important goal mandates that both parties set aside any polarizing positions to work toward the best outcome for all stakeholders involved.

Summary of Chapter 2

- Major pharmaceutical companies have professed commitments to expand access in LMICs through equitable and sustainable pricing solutions.
- International differential pricing and intracountry differential pricing principles provide insights into industry’s price-setting drivers and positions.
- Preparation, preparation, preparation—do your homework! Research both sides and be clear on your nonnegotiable conditions. Also consider the industry’s position or constraints to help identify win-wins. Going into a negotiation without a clear and comprehensive understanding of all the factors involved—only achieved through diligent preparatory work—is a prescription for failure.

Chapter 3.

Managing Negotiations and Long-Term Relationship Management

This chapter focuses on the heart of the negotiation process, the stage when both parties get together to shape out the deal or agreement. As previously discussed, negotiation is all about preparation; approach the negotiating table only after you have developed logical, clearly thought-out arguments through careful preparation. Additionally, establishing a good long-term relationship should be one of the goals in the negotiation. If you're negotiating with a large multinational company, it is likely you will negotiate with it again and again, so it's important to establish a long-term perspective.

Useful Strategies to Adopt during Negotiations

Some practical, helpful strategies for managing the actual negotiations are, as follows:

1. Create a positive environment.

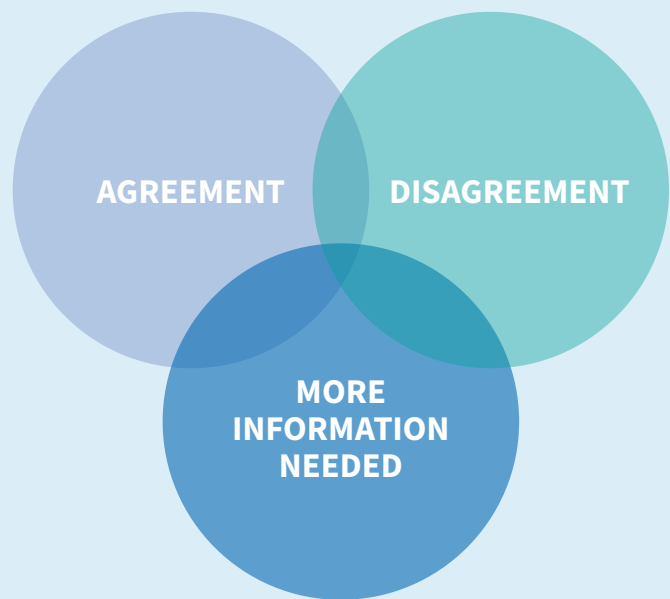
- The space we negotiate in is important. Find a conference room that is spacious enough, has natural light, fresh air, comfortable temperature, and space for breakouts, or “team huddles,” if needed.
- Some people prefer to take walks and talk privately when sensitive issues arise during the negotiations, so be accommodating.
- A hungry stomach is bad for outcomes; plan regular coffee/lunch breaks during the negotiation.
- Have a support team to manage any tasks or errands that come up (e.g., make a reservation, fact-check something on the Internet, call a taxi, etc.)

2. Listen actively and keep your emotions in check.

Communication (both verbal and nonverbal/body language) skills are critical during negotiations. Be an active listener during the negotiation as the goal is to gain a better understanding of what is important to the other side, what limitations they may have, and where they may have some flexibility. Also, try to keep your emotions in check. Losing control could derail the entire negotiations, so always be professional and courteous. However, there are times when despite your best attempt at cordiality and efforts to remain calm, the negotiation dissolves into a conflict. Conflicts in negotiations are common and can typically arise from communication problems, ambiguities around the flexibility of the counterparty (e.g., price/volume discussions in a setting with reference pricing), and personal or value-oriented differences. Box 5 below provides some quick tips on how to reel in the conflicts when they arise.

Box 5: Managing Conflicts in Negotiations

- Don't get angry, it kills the negotiation.
- Take a time-out; sometimes it helps if the team leaders on both sides have a private conversation to decide on new behaviors and carry them out.
- Depersonalize the conflict—separate the issues from the people.
- Identify areas of agreement, areas of disagreement, and issues that need more information to decide whether you agree or disagree; this exercise separates the conflict from the rest of the negotiation and makes it easier to find a solution.



Source: Adapted from presentation by Andreas Seiter given during a workshop on “Negotiating with Pharmaceutical Companies—An Introduction for Practitioners”

3. Always get something in return when you make a concession.

Whenever you are being asked by the other party to make a concession, make sure you receive something in return. You can respond with simple statements such as: “OK, I can consider paying \$X, but in return you have to give me Y.” Always emphasize win-win solutions and look for an integrative solution that allows you to gain additional benefits from the deal.

4. Conduct negotiations in stages if necessary, allowing for adjustments and recalibration.

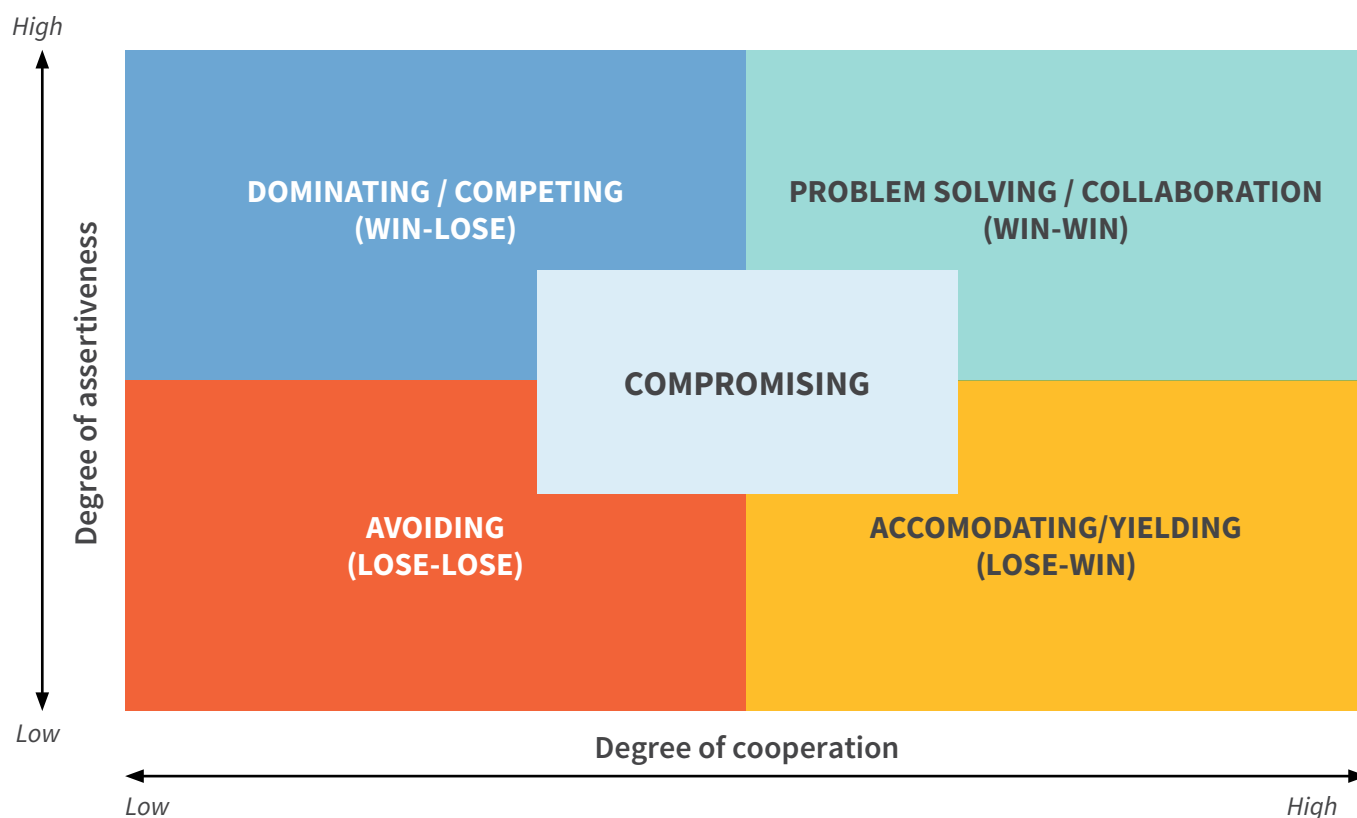
Remember that, as payer, you are setting the rules for negotiations. You can define the agenda, set time limits, negotiate in stages rather than trying to reach agreement in the first round. If necessary to make progress, you can also request that the other side involves senior executives with more decision-making power.

5. Always remember your BATNA

During negotiations, remember your BATNA and consider options better than BATNA but below your original goal if this goal seems too hard to attain. However, if the other party comes up with an ultimatum that you absolutely can't live with, be prepared to postpone, escalate to a higher level, or ultimately walk away.

6. Avoid alienating strategies

Giving ultimatums such as “take it or leave it!” or playing the good cop, bad cop scenarios may sometimes work, but these hard-line tactics come with risks. The risk of being too tough or assertive during a negotiation is that you end up with a less-than-collaborative solution (see Figure 3 below), potentially discouraging your clients from pursuing any further negotiations with you.

Figure 3: Segmented Behavior Matrix

Source: David Henshall, "Developing Differentiated Negotiation Strategies." <http://purchasingpractice.com/developing-a-differentiated-negotiation-strategy/> (accessed March 7, 2022).

7. Finalize the agreement

The end point of a negotiation is when both parties agree on the way forward. Thus, once you've arrived at this point in your negotiations, write down the details of the agreement. It is best if both parties review the written agreement to make sure it says what was intended. The agreement should include details on how the agreement would be implemented and measured, the duration of the agreement, and trigger for review.¹³ Depending on the type of agreement drawn up, some additional questions to discuss and confirm at this final point in the process are (i) How will parties manage any unexpected results from the agreement, and (ii) What monitoring mechanisms will be established to ensure compliance with the agreement? After these details have been firmed up, the agreement documents need to be signed and any follow-up needed done via appropriate letters or e-mails. The final step of approving the agreement found at the negotiation table may not be with the negotiation team but with another body (e.g., health insurance board). In this case, the negotiation is concluded with a joint proposal to the decision makers that is signed by the negotiating parties. Finally, it is always important to keep in mind that every negotiation is a learning opportunity for the next. Throughout the process, take notes of any issues or failures on both sides that come up, so if there is another negotiation, those issues will be discussed in greater detail.

¹³ Marianne Klemp, Katrine Frønsdal, and Karen Facey. 2011. "What Principles Should Govern the Use of Managed Entry Agreements?" *International Journal of Technology Assessment in Health Care* 27: 77–83. 10.1017/S0266462310001297. https://www.researchgate.net/publication/49780871_What_principles_should_govern_the_use_of_managed_entry_agreements.

Long-Term Relationship Building and Management

When negotiating, one of your primary goals should be about establishing a long-term relationship with the drug manufacturer (Box 6), especially if it is a large multinational company. Given its market prowess, it is likely you will negotiate with it again and again, so it's important to establish a collaborative, positive tone that will yield better, future outcomes, even if the first negotiation does not go as planned. Also, remember that the manufacturer likely has the same goal of a long-term relationship.

Box 6: Long-Term Relationship Building—Q&A Discussion with Experts

Q: What are the potential benefits of a long-term relationship with R&D-based pharmaceutical manufacturers?

A: R&D companies have the most knowledge about the medicines they make and their potential impact on improving patient outcomes. This is not surprising as they have access to top clinical experts throughout the entire R&D process and are an excellent source of evidence-based information that could be useful in educating your doctors, nurses, and other health care professionals. A long-term relationship could also potentially evolve into a project-related partnership. In this type of partnership, your government, industry, and a third party (financing partner) join forces to improve access to certain therapies for diseases (e.g., sickle cell anemia) in LMICs. Other examples of project-related partnerships could involve a consortium of drug companies that set up a regional clinical trial hub in your country; besides gathering vital disease information monitoring data, the hub could create additional training and employment opportunities for your country. It is important to point out that while big pharmaceutical companies have the incentive to engage in such partnerships, newer, often smaller biotech companies do not necessarily have the same interest in fostering long-term partnerships. Currently, a significant number of innovative HCMs are being developed by smaller start-up companies that have a different incentive structure. Ultimately, however, companies today understand that beyond the net price-volume component, there must also be commitment on their part to promoting education on the drug, training staff, and supporting infrastructure development if the drug is to be successful in the health marketplace.

Q: How does long-term thinking influence preparation and negotiation strategies?

A: Since companies (larger vs. smaller) may or may not be interested in pursuing a long-term relationship, one helpful approach when preparing for negotiations is to adopt different approaches depending on who you are negotiating with. For example, a large biotech manufacturer with a portfolio in cancer care might be more interested in strengthening oncologic clinical pathways within your country compared to other companies. However, integrating these additional benefits is not something that is accomplished in one negotiation or in a series of negotiations—it takes time. Ideally, you will want to separate discussions on long-term infrastructure investments from the actual price negotiations.

Source: Adapted from discussion with between participants and experts during the JLN learning exchange on Negotiated Solutions for Purchasing High-Cost Medicines, October 2021- January 2022.

Summary of Chapter 3

- The physical space where negotiations take place is just as important as everything else, so ensure you have a comfortable and calm environment.
- Be professional and courteous during the negotiations; communicate clearly and be willing to listen. Compromise when needed but always get something in return.
- Conflicts in negotiations do arise—managing them properly will ensure they do not derail the negotiations.
- Maintaining a long-term relationship with pharmaceutical manufacturers is important—it could yield additional benefits, including project-related partnerships that bring about more transformational change to improving your health system

Conclusion

This Practitioner’s Guide offers a bird’s-eye view into the theory and practice of negotiated solutions for purchasing high-cost medicines, based off the learning and discussion from the JLN learning exchange. Unlike generic medicines, high-cost medicines may require managed entry agreements (MEAs) that allow both the payer and provider to share the financial risks associated with the introduction of a new, pharmaceutical technology. MEAs are popular in high-income countries, but low-and lower-middle-income countries (LMICs) have limited experience with their use. Tenders and reverse auctions are tools that can be appropriate, if there are therapeutically equivalent alternatives available.

To equip stakeholders in LMICs with the knowledge and tools for negotiating these agreements, this Guide begins with insights into the various types of agreements and then moves on to highlight the necessary stages of negotiations—from doing the initial preparatory work (picking out your team, setting objectives, and establishing shared goals, etc.) to managing the actual negotiations and to finalizing agreements. The negotiation process is designed to achieve the best possible outcome, and preferably one in which everyone gains something (win-win-win solution for patient, payer, and the company). Consequently, it’s best to think of ways to work as partners, not as adversaries, with your industry counterpart. Even though pharmaceutical company negotiation teams may be more oriented toward short-term gains, the long-term relationship is also of high value to them and could bring important additional benefits to enhancing and strengthening your health system. Many companies have made statements about their commitment to patient access and affordability—payers can use the negotiations to remind them of their pledges to reach the best outcome for patients.

As the global community continues to battle a COVID-19 pandemic that has disproportionately shifted scarce resources away from the care and treatment of other diseases, countries’ ability to address and respond to noncommunicable diseases has been severely impacted. For LMICs, MEAs could offer one opportunity to get back on track—they create access to life-changing innovative interventions and therapies that could help save lives and are worth a closer look by practitioners and policy makers alike.

JOINTLEARNINGNETWORK.ORG



**JOINT
LEARNING
NETWORK**

For Universal Health Coverage