Checklist

Establishing a Drug Pricing Strategy

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An effective drug pricing strategy requires sustained corporate planning to understand and establish fair pricing in each market where a product is or will be commercialized. This strategy necessarily must include early planning at the development stage, close monitoring of legislative and regulatory pricing reforms in key markets, cross-functional and cross-jurisdictional collaboration across multiple disciplines within an organization, and sensitivity to political sentiment surrounding drug prices.

The following checklist outlines high level action items, structural considerations, and substantive issues for pharmaceutical companies and their investors to consider to establish a thoughtful, holistic, and resilient drug pricing strategy for their development programs.

Pricing Across the Product Life Cycle

- ☐ Determine country sequencing in key markets.
- ☐ Engage in early pricing analyses in the U.S. for clinical stage products in light of Inflation Reduction Act (IRA) and other pricing reforms.
- ☐ Periodically revisit pricing analyses for clinical stage products as clinical trial developments unfold and impact potential approvals, orphan status, or future product indications.
- ☐ Anticipate shorter "pricing cliffs" in light of IRA-imposed ceiling prices (nine years for small molecules and 13 years for biologics), unless an exception applies.
- ☐ Evaluate the pricing impact of fixed combination products, orphan status, approvals of multiple indications, and other product-specific features under the IRA.
- ☐ Continue evaluating pricing strategies and related solutions for late-life cycle products (including authorized generics), particularly in light of Medicare and Medicaid inflation rebates, Medicaid rebate reforms, and government-imposed ceiling price programs.

Monitor for Pricing & Reimbursement Reforms at Federal & Local Levels in Key Markets

- ☐ In the U.S., expect ongoing dialogue on pricing reforms and updates from the legislative branch, the executive branch, or both.
- ☐ Expect States to continue implementing a patchwork of drug pricing legislation, including prescription affordability boards and price transparency initiatives that require burdensome reporting in the event of a new drug launch or price increase.
- ☐ Expect government-driven innovations in pricing and payment models for cell and gene therapies to extend to other specialty products, including outcome-based payment models collectively undertaken by the Centers for Medicare & Medicaid Services on behalf of state Medicaid programs.
- ☐ Monitor for continued pressure on pricing in countries with existing controls and watch for countries that might adopt new controls.
- ☐ Monitor for reforms to external reference pricing models (e.g., including in Canada, France, Germany, Italy, the Netherlands and Spain).
- ☐ Monitor for changes in country sequencing for jurisdictions that have adopted international reference pricing.

Establish a Global Strategy for Engagement & Advocacy

- ☐ Ensure mechanisms are in place to identify efforts to cut reimbursement or institute price controls at their early stages; engage early with government authorities that are considering price controls or reimbursement cuts.

- ☐ Engage in advocacy with relevant governmental policymakers to ensure appropriate awareness of the potential disruption to patient access, research and development programs, and provider financial viability that could be caused by such proposals.

- ☐ Engage with relevant governmental regulatory authorities to appeal reimbursement decisions, where relevant.

Litigation & Government Investigation Readiness

- ☐ In the U.S., litigation and government investigation readiness is another critical component of a comprehensive strategy.

- ☐ Recent IRA pricing litigation demonstrates the importance of moving swiftly and possessing a deep and strategic understanding of the reimbursement regime at issue.

- ☐ In the U.S., litigation readiness may include a multijurisdictional strategy and nuanced consideration of Medicare and Medicaid pricing laws as well as constitutional and Administrative Procedure Act arguments that may support industry viewpoints.

- ☐ In E.U. member states, where litigation on pricing and reimbursement takes different forms—internal appeals, arbitration, administrative or civil courts—the readiness to litigate is becoming increasingly important as scrutiny of companies' pricing strategies increases.

- ☐ Chinese authorities have attempted to use antitrust law to force multinational drug companies to reduce drug prices, and litigation and investigation preparedness is critical.

Contingency Plan

- ☐ Given near and long-term uncertainties in drug cost containment efforts across multiple markets, consider pricing strategies from multiple angles, including whether it is appropriate or feasible to pivot to alternate market access strategies.

- ☐ Expect novel payment and reimbursement models for innovative medicines. Examples include subscription-style payment models, warranty models, and value-based arrangements that tie product pricing or payment to specific health outcomes. Value-based, outcomes-based or subscription model market access strategies may or may not be viable for all therapies.

- ☐ Continue to evaluate initial clinical, economic, and other assumptions that may have been used to formulate strategies for health technology appraisals. Health technology assessment bodies conduct cost-effectiveness assessments to determine whether particular treatments should be made available to patients under national health systems.

- ☐ Closely study publicly available use cases (e.g., the Centers for Medicare and Medicaid Services Cell and Gene Therapy Access Model) as sample case studies, evaluating both pros and cons emanating from the applicable models.

Pricing Governance & Compliance Framework

- ☐ Establish a cross-functional pricing committee that will stay abreast of legislative and regulatory pricing reforms across relevant markets and guide multidisciplinary pricing decisions to align with the company's mission and with applicable laws.

- ☐ Develop written policies and procedures to govern pricing and discount practices across applicable classes of trade, accounting for pricing and reimbursement reforms, and in compliance with applicable law.

- ☐ Designate pricing strategy and decision-making as confidential and proprietary trade secrets in documentation to protect various rights and identify the roles and responsibilities within the organization that are privy to the strategy before it becomes public.

- ☐ Provide regular and periodic training on applicable pricing and discounting policies and procedures to all personnel responsible for pricing and pricing-related activities.

- ☐ Retain knowledgeable personnel to manage day-to-day pricing operations, including experienced government price reporting and market access personnel; secure resources to vet and outsource relevant activities, where appropriate and needed, to reputable experts.

- ☐ Engage in regular auditing and monitoring of compliance with company policies and procedures and key pricing and discounting laws, including the federal Anti-Kickback Statute, government health care program price reporting requirements, and state price transparency laws.