

ACCESS Vision 2030

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Strategic Vision: Revolutionizing Market and Patient Access

Position the ACCESS Forum as a catalyst for the advancement and transformation of the market access profession, empowering the forum to support and lead the necessary growth and evolution in this dynamic field.

Market and Patient Access is a core strategic pillar in life sciences essential for driving success in the rapidly evolving healthcare landscape. In a world where patient needs, regulatory demands, and healthcare costs constantly shift, access strategies must adapt to ensure that innovative, effective therapies reach the right patients at the right time, right price, and through effective channels.

1. Defining Market and Patient Access:

Market access ensures that innovative treatments achieve insurance coverage at a reasonable price for both payers and drug manufacturers, facilitating reimbursement and timely availability. Patient access, on the other hand, focuses on an individual's ability to obtain a prescribed drug when clinically appropriate, without undue financial or administrative barriers. Together, they form the foundation of an integrated healthcare system that bridges innovation with real-world patient benefit.

2. Patient-Centered Approach to Market Access:

Patient access begins with understanding patient needs, enhancing their experience, and ensuring equitable affordability and access. This approach requires that every strategy, from research to the adoption of novel interventions in the healthcare system, considers the patient experience enabling tailored approaches that improve quality of care and patient outcomes strengthen provider-payer relationships, and deliver meaningful value to healthcare systems.

3. Core Strategic Pillars:

- **Value-Driven Strategies and Evidence:** Demonstrating clinical and economic value to stakeholders is essential. Market access teams must present high quality clinical trials that are designed to meet the evidentiary needs of both regulators and payors as well as robust real-world evidence to substantiate therapeutic benefits, patient health outcomes, and cost-effectiveness, impacting pricing, reimbursement, and adoption.

- **Collaborative Innovation:** Effective market and patient access strategies depend on integration with R&D, regulatory, commercial, health economics and outcomes research (HEOR), patient advocacy, and medical affairs teams. Market access teams are evolving from support roles to strategic partners, making cross-functional collaboration vital to drive strategic tradeoffs to reflect access in broader organizational goal and stakeholder needs.
- **Timely Stakeholder Engagement:** Early engagement with payers, providers, regulatory authorities, patient advocacy groups, policymakers, and health technology agencies helps navigate access challenges, remove non-price barriers by strengthening healthcare systems in partnership with stakeholders, and accelerates the journey from approval to market entry.
- **Operational Excellence:** Access teams must embrace operational improvements, artificial intelligence, continually upskill professionals, leverage data-driven insights, and adopt agile, data-backed decision-making processes to remain competitive in global markets.

4. A Framework for the Future:

Through partnerships with leading market access, pharmaceutical, biotech, and MedTech leaders and experts, ACCESS Forum champions the transformation of market and patient access by helping companies and stakeholders develop resilient professionals and optimize access functions and processes. This evolution ensures that innovations reach patients efficiently while meeting the diverse demands of payers, regulators, providers, patients, and healthcare systems. With a commitment to operational excellence, enhanced collaboration, and a patient-first approach, this strategic framework equips companies to anticipate industry shifts, navigate complexities, and establish themselves as key partners in global healthcare.

Five Pillars for Market & Patient Access Vision 2030:

We believe that leaders in market and patient access should focus on five key priorities to achieve the ACCESS vision:

1. **Patient-Relevant Value Proposition:** Build access strategies that prioritize the needs and preferences of patients, using an evidence-based value proposition that resonates with all stakeholders. Address diverse aspects of value including clinical effectiveness, quality of life, cost-effectiveness, pricing models and strategies, and societal impact—to align with the priorities of patients, payers, and policymakers and drive broad support.
2. **Data-Driven Market Access Strategies:** Utilize high quality clinical trials designed to meet the evidentiary needs beyond regulators, as well as real-world evidence,

health economic models, and advanced analytics to optimize access strategies and reimbursement.

3. **Strategic Stakeholder Engagement:** early conversation with HTA organizations and payers to understand their perspectives while creating a dialogue to enhance understanding about the priorities and limitations of life science companies. Build proactive, tailored relationships with providers, and regulators to accelerate market entry.
4. **Cross-Functional Collaboration and Integration:** Align internal functions and processes seamlessly to enable cohesive market access planning and execution.
5. **Innovative Access Channels and Policy Shaping:** Embrace technology (AI....) and innovative policy engagement to create new access pathways and drive the development of constructive changes in regulatory and market access processes leveraging existing regulatory and access agencies globally.

Key Environmental Trends Shaping Market Access

These critical environmental trends are reshaping the market access landscape, influencing strategies, priorities, and competencies required to ensure patient access and sustainability in healthcare systems.

1. **Shortage of Skilled Market Access Professionals**
The growing demand for specialized market access roles outpaces the current supply of trained professionals, creating a need for targeted workforce development to bridge skill gaps and support sector growth.
2. **Affordability and Sustainability Concerns in Health Systems**
With escalating healthcare costs, payers and providers are under pressure to ensure the sustainability of health systems while maintaining affordability for patients, prompting market access strategies that balance cost-effectiveness and value for money with broad patient access. Changes in health system incentive and operational models are also changing rapidly in several markets, requiring up-to-date knowledge of all aspects of the patient access infrastructure.
3. **Emphasis on Value-Based Assessments**
Increasing reliance on value-based frameworks by payers and HTA bodies demands that market access strategies demonstrate not only clinical efficacy but also economic value, underscoring the need for robust health economic models and real-world evidence.
4. **Global Push for Universal Health Coverage**
International efforts to expand healthcare access drive demand for therapies that

meet broad population needs at accessible price points, influencing market access strategies to prioritize affordable and scalable treatments.

5. Focus on Health Disparities and Health Equity

The spotlight on addressing health disparities compels market access professionals to ensure equitable access across diverse populations, incorporating strategies that reach underserved groups and consider social determinants of health.

6. Expanded Use of Accelerated Regulatory Pathways

Accelerated pathways are increasingly utilized for innovative therapies, especially for conditions with high unmet needs, prompting market access and regulatory teams to align early to develop evidence to meet expedited approval criteria or, where necessary, set up conditions for coverage with evidence development.

7. Growth in Curative Therapies for Specific Subpopulations

Advances in precision medicine and curative therapies for specific patient populations are transforming treatment landscapes, requiring market access strategies tailored to the unique needs and challenges of these specialized groups.

8. Expanding Cancer and Rare Disease Treatment Portfolios

The growing number of treatments for oncology and rare diseases necessitates strategies that address unique pricing, reimbursement, and patient access challenges associated with these high-cost, high-value therapies, including increasing use of treatment regimens that combine expensive therapies.

9. Evolving MedTech Pathways and Access

Rapid MedTech innovation, driven by AI and emerging technologies, is prompting regulatory shifts in the US and Europe. However, inadequate reimbursement limits patient and clinician access, highlighting the need for equitable solutions.

10. Increased Use of Digital Health Technologies

Digital health tools, such as telemedicine, remote monitoring, and health apps, are transforming patient engagement and access, requiring market access teams to integrate digital solutions into patient access strategies.

11. Advances in Real-World Data, Analytics, and Artificial Intelligence (AI)

The availability of high-quality real-world data and advancements in analytics and AI are enabling deeper insights into treatment outcomes and patient experiences, enhancing evidence generation and supporting more personalized market access approaches.

12. Large-Scale Policy Changes, Including IRA and HTAR

Major policy changes, such as the Inflation Reduction Act (IRA) in the US and Health Technology Assessment Regulation (HTAR) in the EU, are reshaping reimbursement landscapes and introducing new compliance requirements, prompting market access teams to adapt to rapidly evolving regulatory environments, and payer and patient data needs and expectations.

Essential Core Functional Competencies for Market Access Professionals: Strategic and Technical Skills for Growth, Impact and Success

In an increasingly complex healthcare landscape, market and patient access professionals require a robust combination of strategic and technical competencies to achieve impactful, sustained growth to ensure success. These foundational competencies encompass both essential technical skills and adaptive leadership qualities, enabling professionals to excel across strategic and operational domains. This well-rounded approach equips market access professionals to meet both the technical demands and the adaptive challenges of their roles, advancing patient-centered access initiatives and fostering resilience in a rapidly evolving industry. Recognizing this complexity, ACCESS Forum is a key nexus for these disciplines to come together, integrate, and share best practices.

1. Strategic Pricing and Reimbursement Expertise

Developing and executing flexible pricing and reimbursement strategies is key to product affordability, market sustainability, and alignment with payer needs.

- Portfolio optimization: Provide strategic pricing expertise to asset prioritization (internal and external assets) and indication sequencing, considering various geographic/ country requirements and opportunities.
- Early Engagement: Proactively engage with payers during development to align on evidence needs and budgetary constraints, setting the stage for efficient market entry.
- Flexible Pricing Strategies: Skill in implementing adaptable pricing models, such as value-based and risk-sharing agreements, to address diverse stakeholder requirements.

2. Negotiation Preparation and Execution: Effective negotiation skills are essential for achieving optimal market access outcomes. Market access teams must excel in both preparation and in-the-moment negotiation to secure sustainable agreements that align with company objectives and meet payer and stakeholder requirements, ultimately benefiting both the company and the patients served.

- **Strategic Alignment and Goal Setting**
Define clear, measurable objectives aligned with the market access strategy and ensure internal alignment with cross-functional stakeholders (e.g., commercial, finance, medical, regulatory, legal) to establish a unified position and acceptable terms.
 - **Understanding and Engage Stakeholders**
Conduct stakeholder mapping to understand payer priorities, values, and constraints, and analyze their decision-making processes, reimbursement criteria, and past negotiation outcomes.
 - **Value Proposition Development and Adaptation**
Craft a compelling value story for payers that emphasizes economic, clinical, and humanistic benefits, supported by health economics and outcomes research (HEOR) data to substantiate claims and pricing models.
 - **Scenario Planning and Objection Handling**
Anticipate payer, political, and societal objections with data-driven responses and develop multiple negotiation scenarios, including best and worst-case outcomes with defined fallback positions.
 - **Post-Negotiation Analysis**
Review the negotiation process to identify successes and areas for improvement, documenting insights to enhance future negotiation strategies.
3. **Operational pricing** is a dynamic process that extends beyond price setting, involving the implementation and management of pricing strategies across diverse countries and payer systems. It aligns global objectives with local market needs while ensuring compliance with regulatory and legal requirements. This includes navigating regulatory, payer and patient journey complexities, responding to competition, and addressing evolving payer requirements to maintain sustainable pricing worldwide.
- **Negotiation, Payer Engagement & Contract Management** – Training teams to handle pricing negotiations and payer objections, while also developing tailored pricing offers and conducting contract analysis to ensure competitive and compliant pricing solutions across markets.
 - **Innovative Pricing Models & Life Cycle Management** – Adapting advanced pricing strategies, such as performance-based contracts, subscription models, and indication-based pricing, while continuously adjusting prices throughout the product life cycle in response to competitor actions, budget changes, and preparation for loss of exclusivity (LOE).
 - **Gross-to-Net Management & Financial Reporting** – Overseeing the gross-to-net process, optimizing revenue recognition, and ensuring compliance with financial reporting requirements for accurate, transparent pricing management.

- **International Price Referencing & Trade Compliance** – Addressing the challenges of global price referencing and navigating trade regulations to maintain competitive pricing across multiple regions.
- **Pricing Data Management** – Managing internal pricing databases and tools to ensure consistent, accurate pricing information is accessible and actionable across global teams.

4. **Data Proficiency and Evidence Generation**

Expertise in generating relevant and robust clinical and real-world data, combined with advanced data proficiency, strengthens evidence and supports product positioning.

- **Robust Trial Design:** Provide advice on the design of clinical trials that provide clear evidence of efficacy, effectiveness and safety, ensuring alignment with payer and patient needs.
- **Health Economic Models:** Competency in creating economic models to demonstrate cost-effectiveness and reinforce product value.
- **Real-World Data:** Leverage real-world data alongside clinical trial evidence to validate product value in real-world settings. Data should be presented clearly and compellingly to effectively communicate key insights to payers.
- **Data Analytics:** Collaborate with statistical and researcher to mobilize key functions early ensuring statistical analyses and economic models are well designed, appropriately analyzed and results are correctly reported and communicated. Identify gaps in team structures and understand how to mobilize organizational resources to ensure that all needed expertise is engaged?
- **Comparative Effectiveness:** Conduct studies comparing new treatments with existing options to highlight product advantages.
- **Patient experience data generation, analytics and interpretation** as integral part of the relevant value proposition

5. **Health Technology Assessment (HTA) Navigation and Policy Insight**

Navigating HTA processes and understanding policy environments are crucial for timely reimbursement approvals across varied regulatory landscapes.

- **Tailored Dossiers:** Develop market-specific, comprehensive submissions that meet the requirements of each HTA body.
- **Local Adaptations:** Adapt global evidence to local HTA standards, ensuring relevance and compliance.
- **Early Dialogues:** Engage HTA bodies early to align on evidence needs and expectations, fostering smoother market access.

- Policy Insight: Maintain a strong understanding of local, regional, and national policies, enabling informed and proactive adaptation to policy shifts.

6. **Comprehensive Patient Access Programs and Stakeholder Collaboration**

Designing and managing patient access initiatives that focus on affordability, accessibility, and collaborative stakeholder relationships is essential to product success.

- Affordability Support: Create patient assistance and co-pay programs that reduce financial barriers and enhance access.
- Access Strategies: Implement expanded access and compassionate use programs to provide therapies to patients with urgent needs.
- Patient Education and Support: Develop educational initiatives that improve adherence, optimize patient outcomes, and foster long-term engagement.
- Stakeholder Collaboration: Ability to co-create and maintain strong relationships with internal and external stakeholders, ensuring alignment and support.

7. **Health Policy Advocacy, Patient Advocacy, and Stakeholder Engagement**

Engage collaboratively with policymakers, patient groups, and the wider community to support regulatory changes and amplify patient perspectives in decision-making.

- **Policy Collaboration:** Work with policymakers to advocate for reforms that improve patient access and healthcare sustainability.
- **Advocacy Partnerships:** Build relationships with patient advocacy groups to align on shared goals that inform healthcare decisions.
- **Educational Outreach:** Provide information to providers and payers on product benefits to support informed choices.
- **Advisory Boards:** Establish advisory boards with key opinion leaders to gather insights and strengthen community support.

8. **Global Regulatory and Market Access Harmonization**

Harmonizing regulatory and access strategies across markets facilitates efficient product launches and helps meet global healthcare needs.

- Global Regulatory Strategy: Design strategies that address diverse regulatory requirements, enabling timely and compliant product submissions.
- Harmonization Initiatives: Participate in international harmonization efforts (e.g., ICH) to streamline processes and expedite approvals.
- Expedited Pathways: Use accelerated pathways for critical therapies addressing unmet needs to achieve faster market access.

- Participate in efforts to harmonize HTA evidence requirements and processes

9. Adoption of Technological Innovation and Adaptive Leadership

Embracing technological solutions and leading adaptively through dynamic environments are critical for driving access and engagement.

- Digital Solutions: Implement digital tools for regulatory submissions and tracking, reducing processing times and enhancing transparency.
- Telemedicine and Digital Health: Invest in telemedicine platforms to improve patient engagement and accessibility.
- Thought leadership by partnering with academia and policy groups to drive development of innovative methodologies, value frameworks, access pathways and funding models to accelerate access.
- Collaborative Innovation: Partner with pharma and biotech companies to accelerate the development and commercialization of advanced therapies using AI tools.
- Partner with the patient community to understand their preferences and needs, so that AI technology, digital tools, clinical endpoints patient reported outcomes are patient relevant outcomes coming from various data sources.
- Adaptive Leadership: Demonstrate the ability to lead and respond effectively to rapid changes, adapting strategies to evolving internal and external conditions.

Call to Action: Strengthening the Market Access Profession

In response to the rapid evolution of the healthcare environment, market access professionals face an urgent need for enhanced training, education, and professional development. The entire field also benefits from training and sharing of approaches and best practices in actively overcoming access hurdles. The establishment of focused, well-resourced pre-competitive forums for dialogue and exchange of ideas is essential to clarify needs and foster a collaborative agenda that addresses the demands of today's and the future healthcare landscape. Such forums provide a platform to strengthen the market access workforce and drive innovation, helping to set policy directions for value-based healthcare that align with patient needs, alongside payers' funding considerations and health system sustainability.

Implications for the Market Access Forum

1. Develop a skilled and adaptable workforce by prioritizing programs that enhance technical, strategic, and communication competencies in market access.

2. Facilitate new learning opportunities between HTA bodies, payers, and market access professionals to foster collaboration and shared insights.
3. Establish structured systems that enable market access professionals to build learning relationships with experts in HTA, government, and health policy.
4. Explore and promote alternative operational models that help life sciences organizations adapt to regulatory shifts, policy changes, and emerging trends.
5. Champion innovation in market access strategies to ensure alignment with the evolving healthcare landscape and patient needs.

These initiatives underscore the Access Forum's pivotal role in shaping a resilient and forward-looking market access profession, capable of advancing patient access, supporting regulatory agility, and driving industry-wide success.

Drive Innovation: By fostering creative solutions and developing strategies to navigate and overcome market access challenges.

Strengthen the Workforce: By enhancing the capabilities and skills of professionals within the market access field.

Shape Policy: Through collaborative efforts that steer the development of value-based, patient-centric healthcare policies.

Ensure Holistic Alignment: By synchronizing patient needs with payer priorities and broader health system sustainability.