Advanced Skill Certificate in Market Access for Pharmaceuticals

Market Access Policy and Advocacy

Access Accelerated is a term used in the context of market access to describe initiatives that aim to improve access to healthcare products, particularly in low- and middle-income countries, by accelerating the availability of these products. Related terms include equitable access and universal health coverage. Access Accelerated brings together stakeholders from the pharmaceutical industry, governments, and non-governmental organizations to address the challenges of accessing healthcare products in resource-poor settings. For example, through Access Accelerated, companies can work with governments to implement price reductions and tiered pricing strategies to make their products more affordable in different markets.

Adaptive Pathways is a concept in regulatory science that involves the use of iterative and adaptive approaches to the development and approval of new medicines. Related terms include personalized medicine and precision medicine. Adaptive Pathways aim to facilitate the development of medicines for patients with unmet medical needs by allowing for the early involvement of stakeholders, including patients, clinicians, and regulators, in the development process. This approach enables the flexible and efficient development of medicines, particularly for rare or orphan diseases.

Affordability is a critical concept in market access that refers to the extent to which patients can afford to pay for healthcare products and services. Related terms include cost-effectiveness and cost-benefit analysis. Affordability is influenced by factors such as price, reimbursement policies, and out-of-pocket costs. For example, a high-priced medicine may not be considered affordable in a low-income country, even if it is effective in treating a particular disease. Companies can improve affordability by implementing pricing strategies such as tiered pricing or differential pricing.

Aggregate Data is a term used in health economics to describe data that is collected and analyzed at the population or aggregate level, rather than at the individual level. Related terms include real-world evidence and real-world data. Aggregate data can be used to inform healthcare decisions, such as the development of guidelines and formularies, and to evaluate the effectiveness and cost-effectiveness of healthcare interventions. For example, aggregate data on the prevalence and incidence of a particular disease can be used to estimate the budget impact of a new treatment.

Benefit-Risk Assessment is a concept in regulatory science that involves the evaluation of the benefits and risks associated with a particular medicine or healthcare product. Related terms include risk management and pharmacovigilance. Benefit-Risk Assessment is a critical component of the regulatory review process, as it enables regulators to make informed decisions about the approval and marketing of new medicines. For example, a benefit-risk assessment may involve evaluating the efficacy and safety of a new medicine, as well as its potential impact on public health.

Budget Impact Analysis is a term used in health economics to describe the evaluation of the potential financial impact of a new healthcare intervention on a healthcare system or payer. Related terms include cost-effectiveness analysis and cost-benefit analysis. Budget Impact Analysis is used to inform

reimbursement decisions and to evaluate the affordability of new treatments. For example, a budget impact analysis may estimate the total cost of a new medicine, including the cost of the medicine itself, as well as any associated costs, such as administration and monitoring costs.

Clinical Evidence is a term used in regulatory science to describe the data and evidence generated from clinical trials and other clinical studies. Clinical Evidence is used to support the approval and marketing of new medicines, as well as to inform clinical practice and guideline development. For example, clinical evidence may include efficacy and safety data from randomized controlled trials, as well as observational data from real-world studies.

Compassionate Use is a concept in regulatory science that involves the use of unapproved or investigational medicines to treat patients with serious or life-threatening diseases. Related terms include expanded access and emergency use. Compassionate Use programs are designed to provide patients with access to potentially life-saving treatments, while also generating data and evidence to support the approval of these treatments. For example, a compassionate use program may provide patients with access to a new cancer treatment that has not yet been approved by regulatory authorities.

Cost-Effectiveness Analysis is a term used in health economics to describe the evaluation of the costs and effects of different healthcare interventions. Related terms include cost-benefit analysis and cost-utility analysis. Cost-Effectiveness Analysis is used to inform reimbursement decisionsvalue of different treatments. For example, a cost-effectiveness analysis may compare the costs and effects of a new medicine with those of an existing treatment, in order to determine which treatment provides the best value for money.

Cost-Sharing is a concept in health economics that involves the sharing of costs between payers and patients. Related terms include copayments and coinsurance. Cost-Sharing is used to manage and control healthcare costs, while also providing patients with access to necessary treatments. For example, a cost-sharing arrangement may require patients to pay a copayment or coinsurance for a particular treatment, in order to share the costs with the payer.

Differential Pricing is a concept in market access that involves the use of different prices for the same product in different markets or countries. Related terms include tiered pricing and price discrimination. Differential Pricing is used to improve access to healthcare products, particularly in low- and middle-income countries, by offering lower prices in these markets. For example, a company may offer a lower price for a medicine in a low-income country, in order to make it more affordable for patients in that country.

Early Access Programs are initiatives that provide patients with access to unapproved or investigational medicines, often in serious or life-threatening situations. Related terms include compassionate use and expanded access. Early Access Programs are designed to provide patients with access to potentially life-saving treatments, while also generating data and evidence to support the approval of these treatments. For example, an early access program may provide patients with access to a new cancer treatment that has not yet been approved by regulatory authorities.

Economic Evaluation is a term used in health economics to describe the evaluation of the costs and effects of different healthcare interventions. Economic Evaluation is used to inform reimbursement decisions and to

evaluate the value of different treatments. For example, an economic evaluation may compare the costs and effects of a new medicine with those of an existing treatment, in order to determine which treatment provides the best value for money.

Expanded Access is a concept in regulatory science that involves the use of unapproved or investigational medicines to treat patients with serious or life-threatening diseases. Related terms include compassionate use and emergency use. Expanded Access programs are designed to provide patients with access to potentially life-saving treatments, while also generating data and evidence to support the approval of these treatments. For example, an expanded access program may provide patients with access to a new cancer treatment that has not yet been approved by regulatory authorities.

Formulary is a term used in healthcare to describe a list of medicines or healthcare products that are approved for use in a particular healthcare system or setting. Related terms include preferred drug list and pharmacy benefit management. Formularies are used to manage and control healthcare costs, while also providing patients with access to necessary treatments. For example, a formulary may include a list of generic and brand-name medicines that are approved for use in a particular healthcare system.

Generic Medicine is a term used in pharmaceuticals to describe a medicine that is equivalent to a brand-name medicine, but is often less expensive. Related terms include biosimilar and biogeneric. Generic medicines are used to improve access to healthcare products, particularly in low- and middle-income countries, by offering lower prices for equivalent treatments. For example, a generic version of a cancer treatment may be less expensive than the brand-name version, but still provide the same therapeutic benefits.

Health Economics is a field of study that involves the evaluation of the costs and effects of different healthcare interventions. Related terms include pharmacoeconomics and health technology assessment. Health Economics is used to inform reimbursement decisions and to evaluate the value of different treatments. For example, a health economic evaluation may compare the costs and effects of a new medicine with those of an existing treatment, in order to determine which treatment provides the best value for money.

Health Technology Assessment is a term used in healthcare to describe the evaluation of the clinical and cost-effectiveness of different healthcare interventions. Related terms include health economics and pharmacoeconomics. Health Technology Assessment is used to inform reimbursement decisions and to evaluate the value of different treatments. For example, a health technology assessment may evaluate the costs and effects of a new medical device, in order to determine whether it provides a therapeutic benefit to patients.

Innovation is a term used in pharmaceuticals to describe the development of new and improved healthcare products and services. Related terms include research and development and new product development. Innovation is critical to improving health outcomes and quality of life for patients, as it enables the development of new and effective treatments for diseases. For example, innovation in biotechnology has led to the development of new treatments for diseases such as cancer and rheumatoid arthritis.

Insurance is a term used in healthcare to describe a system of financing healthcare costs, in which individuals or groups pay premiums to a third-party payer in exchange for coverage of healthcare costs. Related terms include reimbursement and health insurance. Insurance is used to manage and control healthcare costs, while also providing patients with access to necessary treatments. For example, a health insurance plan may cover the cost of a particular treatment, such as a cancer treatment, in order to make it more affordable for patients.

Market Access is a term used in pharmaceuticals to describe the process of making healthcare products available to patients in a particular market or country. Related terms include reimbursement and pricing. Market Access involves a range of activities, including regulatory approval, reimbursement, and pricing, in order to make healthcare products available to patients. For example, a company may need to obtain regulatory approval for a new medicine in a particular country, in order to make it available to patients in that country.

Medical Affairs is a term used in pharmaceuticals to describe the department or function responsible for medical and scientific activities, such as clinical trials and medical education. Medical Affairs plays a critical role in the development and commercialization of new medicines, as it provides medical and scientific expertise to support the development and launch of new products. For example, a medical affairs team may be responsible for designing and conducting clinical trials, as well as providing medical education and training to healthcare professionals.

Negotiated Price is a term used in healthcare to describe a price that is negotiated between a payer and a manufacturer or supplier. Negotiated prices are used to manage and control healthcare costs, while also providing patients with access to necessary treatments. For example, a payer may negotiate a discounted price for a particular treatment, such as a cancer treatment, in order to make it more affordable for patients.

New Chemical Entity is a term used in pharmaceuticals to describe a new chemical or molecule that has not been previously approved for use in humans. Related terms include new molecular entity and new active substance. New Chemical Entities are critical to improving health outcomes and quality of life for patients, as they enable the development of new and effective treatments for diseases. For example, a new chemical entity may be developed as a treatment for a particular disease, such as cancer or rheumatoid arthritis.

Out-of-Pocket Costs are a term used in healthcare to describe the costs that patients pay directly for healthcare products and services. Out-of-Pocket Costs are used to manage and control healthcare costs, while also providing patients with access to necessary treatments. For example, a patient may pay an out-of-pocket cost for a particular treatment, such as a copayment or coinsurance, in order to share the costs with the payer.

Patient Access is a term used in healthcare to describe the ability of patients to access healthcare products and services. Related terms include access to care and healthcare access. Patient Access is critical to improving health outcomes and quality of life for patients, as it enables patients to receive the treatments and care they need. For example, a patient may have access to a particular treatment, such as a cancer treatment, through a health insurance plan or government program.

Patient Advocacy is a term used in healthcare to describe the activities and efforts of patients and patient organizations to promote access to healthcare products and services. Related terms include patient engagement and patient empowerment. Patient Advocacy is critical to improving health outcomes and quality of life for patients, as it enables patients to have a voice in the development and delivery of healthcare products and services. For example, a patient advocacy group may work to promote access to a particular treatment, such as a cancer treatment, by advocating for reimbursement and pricing policies that make the treatment more affordable for patients.

Pharmaceutical Policy is a term used in healthcare to describe the policies and regulations that govern the development, approval, and marketing of pharmaceuticals. Related terms include drug policy and medicine policy. Pharmaceutical Policy is critical to improving health outcomes and quality of life for patients, as it enables the development and delivery of safe and effective treatments. For example, a pharmaceutical policy may regulate the approval and marketing of new medicines, in order to ensure that they are safe and effective for use in humans.

Pricing is a term used in healthcare to describe the process of setting the price of a healthcare product or service. Related terms include reimbursement and cost. Pricing is critical to improving access to healthcare products and services, as it enables patients to afford the treatments and care they need. For example, a company may set a price for a new medicine, such as a cancer treatment, based on its value to patients and payers.

Product Lifecycle Management is a term used in pharmaceuticals to describe the process of managing the lifecycle of a pharmaceutical product, from development to launch and post-launch. Related terms include product development and life cycle management. Product Lifecycle Management is critical to improving health outcomes and quality of life for patients, as it enables the development and delivery of safe and effective treatments. For example, a company may manage the lifecycle of a new medicine, such as a cancer treatment, by monitoring its safety and efficacy in clinical trials and post-marketing studies.

Public-Private Partnership is a term used in healthcare to describe a partnership between public and private organizations, such as governments and companies, to promote access to healthcare products and services. Related terms include partnership and collaboration. Public-Private Partnerships are critical to improving health outcomes and quality of life for patients, as they enable the development and delivery of safe and effective treatments. For example, a public-private partnership may work to promote access to a particular treatment, such as a cancer treatment, by providing funding and resources to support its development and delivery.

Quality of Life is a term used in healthcare to describe the overall well-being and quality of life of patients. Related terms include health-related quality of life and patient-reported outcomes. Quality of Life is critical to improving health outcomes for patients, as it enables patients to live full and productive lives. For example, a treatment may improve the quality of life of patients with a particular disease, such as cancer or rheumatoid arthritis, by reducing symptoms and improving function.

Real-World Data is a term used in healthcare to describe data and evidence generated from real-world sources, such as electronic health records and claims databases. Related terms include real-world evidence

and observational data. Real-World Data is used to inform healthcare decisions, such as the development of guidelines and formularies, and to evaluate the effectiveness and cost-effectiveness of healthcare interventions. For example, real-world data may be used to evaluate the effectiveness of a particular treatment, such as a cancer treatment, in real-world settings.

Reimbursement is a term used in healthcare to describe the process of paying for healthcare products and services. Related terms include payment and coverage. Reimbursement is critical to improving access to healthcare products and services, as it enables patients to afford the treatments and care they need. For example, a payer may reimburse the cost of a particular treatment, such as a cancer treatment, in order to make it more affordable for patients.

Regulatory Affairs is a term used in pharmaceuticals to describe the department or function responsible for regulatory and compliance activities, such as regulatory submissions and compliance monitoring. Related terms include regulatory science and regulatory policy. Regulatory Affairs plays a critical role in the development and commercialization of new medicines, as it ensures that companies comply with regulatory requirements and standards. For example, a regulatory affairs team may be responsible for preparing and submitting regulatory applications, such as new drug applications or marketing authorization applications.

Regulatory Approval is a term used in pharmaceuticals to describe the process of obtaining approval from regulatory authorities to market a new medicine. Related terms include marketing authorization and license. Regulatory Approval is critical to improving access to healthcare products and services, as it enables companies to market and distribute new medicines to patients. For example, a company may obtain regulatory approval for a new medicine, such as a cancer treatment, in order to market and distribute it to patients in a particular country or region.

Regulatory Science is a term used in pharmaceuticals to describe the science and research that underlies the development and evaluation of new medicines. Related terms include regulatory affairs and regulatory policy. Regulatory Science plays a critical role in the development and commercialization of new medicines, as it ensures that companies develop and evaluate new medicines in a scientific and rational manner. For example, regulatory science may involve the development and validation of new analytical methods or clinical trial designs.

Risk Management is a term used in pharmaceuticals to describe the process of identifying, assessing, and mitigating risks associated with the development and use of new medicines. Related terms include risk assessment and risk mitigation. Risk Management is critical to improving safety and efficacy of new medicines, as it enables companies to identify and address potential risks and hazards associated with their use. For example, a company may develop a risk management plan to identify and mitigate risks associated with a new medicine, such as a cancer treatment.

Stakeholder Engagement is a term used in healthcare to describe the process of engaging with stakeholders, such as patients, healthcare professionals, and payers, to promote access to healthcare products and services. Related terms include stakeholder management and stakeholder relations. Stakeholder Engagement is critical to improving health outcomes and quality of life for patients, as it enables companies to understand and address the needs and concerns of stakeholders. For example, a

company may engage with patient organizations to promote access to a particular treatment, such as a cancer treatment, and to address the needs and concerns of patients.

Tiered Pricing is a concept in market access that involves the use of different prices for the same product in different markets or countries. Related terms include differential pricing and price discrimination. Tiered Pricing is used to improve access to healthcare products, particularly in low- and middle-income countries, by offering lower prices in these markets.

Universal Health Coverage is a term used in healthcare to describe the goal of providing all people with access to essential healthcare services, without financial hardship. Related terms include health for all and equitable access. Universal Health Coverage is critical to improving health outcomes and quality of life for patients, as it enables patients to receive the treatments and care they need, without financial hardship. For example, a country may implement a universal health coverage system, in which all citizens have access to essential healthcare services, without financial hardship.

Value-Based Pricing is a concept in market access that involves setting the price of a healthcare product or service based on its value to patients and payers. Value-Based Pricing is used to improve access to healthcare products and services, as it enables patients to afford the treatments and care they need, while also providing value to payers. For example, a company may set a price for a new medicine, such as a cancer treatment, based on its value to patients and payers, in order to make it more affordable and accessible to patients.