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Access and Affordability Programmes

Reducing inequalities in access to medicines

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Contents

Introduction

Access and affordability programmes (AAPs) are an important component of the strategies of pharmaceutical (pharma) companies. Their purpose is to ensure that patients around the world have equitable access to medicines and health care.

Elizabeth Hampson
Director, Monitor Deloitte

Emerging trends across the life sciences and health care industry, such as patient centricity, value-based health care, 'big data', advanced digital technologies and other disruptive innovations are being reflected in the evolution of AAPs. The COVID-19 pandemic has highlighted the importance of trust in pharma, the need to build resilient health care systems and for equality of access to medicines and health care, having accelerated the transformation and evolution of AAPs.

Based on our experience in supporting pharma companies, together with insights from our proprietary Deloitte Access and Affordability Database (which contains over 400 AAP programmes), we have formed our perspectives on AAPs today and in the future. AAPs are becoming more holistic in nature and are increasingly designed to address the complexities and multiple barriers to access that can arise within a market, whereas in the past they may have focused solely on affordability challenges.

In addition, in their AAPs pharma companies are increasingly engaging with partners across the health care ecosystem, particularly digital tech partners, to integrate tech-led solutions that offer better outreach.

To create strategies for access and affordability, pharma companies should design AAPs that continue to align with industry trends and should consistently test their programmes to ensure they address nuanced access challenges that arise across markets and therapy areas. Moreover, the many new health care challenges that have arisen as a result of the pandemic have highlighted the need for resilient health care systems. In response, pharma companies should focus on access programmes to strengthen health care systems and activities that meet the individual needs of patients within each market and improve overall access to medicine.

> "The COVID-19 pandemic has highlighted the importance of trust in pharma, the need to build resilient health care systems and for equality of access to medicines and health care"

Understanding the importance of AAPs

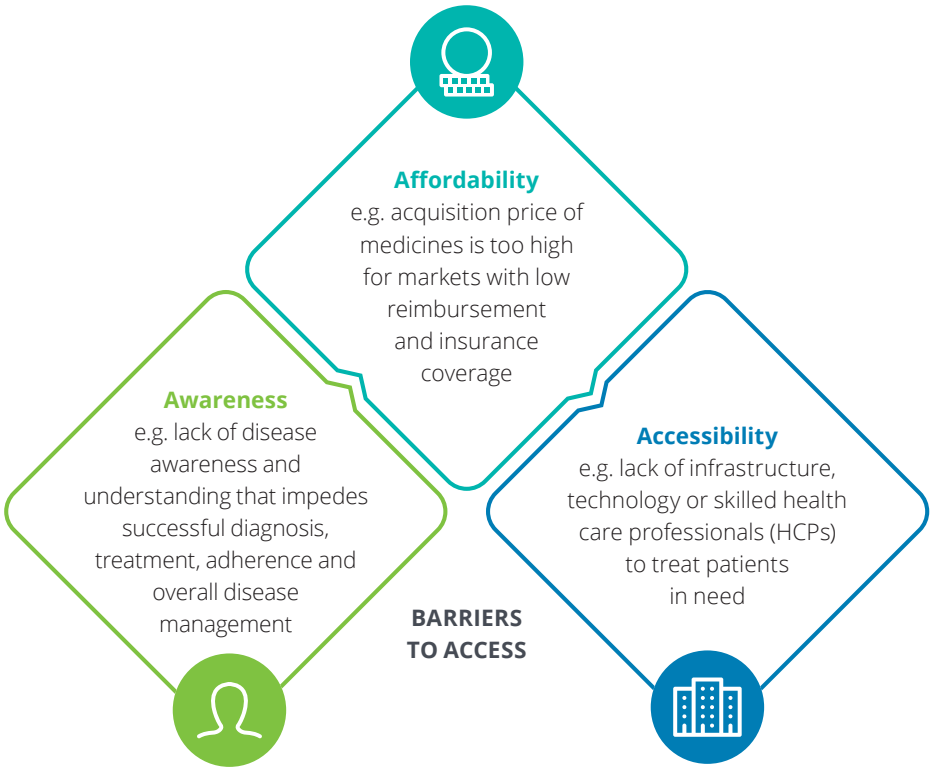
Over one-quarter of the world's population does not have access to essential medicines. For more than two billion people worldwide, medicines may be unaffordable, unavailable, inaccessible or non-quality assured.[1,2] As well as impeding the fundamental right of individuals to maintain their health, this results in a huge burden to global economies and health systems due to high rates of morbidity and mortality.

Whilst inadequate access to medicines and health care is pervasive in low-to-middle-income countries (LMICs), they are not exclusive to them. In some mature markets, such as the US, health care costs are not covered by insurance and patients are required to pay a significant portion of these expenses out of their own pocket. As a result, affordability and access challenges are common throughout poor communities and minority groups in many high-income countries, leading to inequality in health care and poorer health outcomes.

Barriers to access are wide-ranging: social, financial and health care system factors can all affect the ability of patients to receive medication and suitable treatment. In the majority of patient populations, the issues are complex and are likely to involve an interplay of all three factors to varying degrees, depending on the market and the disease (**Figure 1**).

In addition to bringing life-saving medicines to market, pharma organisations recognise the critical role of AAPs in helping to overcome these barriers to access and affordability. Vaccine hesitancy during the COVID-19 pandemic has also highlighted the importance of trust in the pharma industry. AAPs give pharma companies the opportunity to engage with patients and health care providers, and to improve the existing trust deficit.[3]

Figure 1. Barriers to accessing health care are wide-ranging and multi-faceted



Source: Deloitte analysis.

> "Affordability and access challenges are common throughout poor communities and minority groups in many high-income countries, leading to inequality in health care and poorer health outcomes."

AAPs: Reducing health inequality

Millions of patients around the world benefit from AAPs. For example, AstraZeneca has reached over 25 million patients and trained over 130,000 HCP's through AAPs.[4] However, there is still much more to be done. The World Health Organization (WHO) highlights the responsibility and accountability of pharma companies to improve access to their medicines in underserved communities.

The impact of AAPs will vary depending on their intent and scope. For example, an AAP targeting rare diseases may have a significant impact at an individual patient level, compared to a vaccine for a non-communicable disease whose impact may be measured by volume and product reach. AAPs are generally used by pharma in the key therapy areas where they have the biggest potential (and so responsibility) to make an impact.

The Access to Medicine Index monitors and assesses the strategies of pharma companies in this area, and every two years ranks the top 20 companies based on their contribution to achieving equitable access to medicines globally.[5]

A finding in the 'Access to Medicine Index 2021' was that less than half of key products are covered by the access strategies pharma companies in low-income countries (LICs).[6] This highlights the need for pharma companies to focus their AAP strategies on the most deprived geographies in addition to achieving equitable access to medicines and health care globally.

> "The impact of AAPs will vary depending on their intent and scope. For example, an AAP targeting rare diseases may have a significant impact at an individual patient level, compared to a vaccine for a non-communicable disease whose impact may be measured by volume and product reach."

What is an AAP?

Access and affordability programmes (AAPs) are initiatives, usually run by pharma companies, that aim to provide **equitable** and **sustainable** access to **medicines** and health care around the world.

AAPs are generally focused on markets with underfunded health care systems or high out-of-pocket patient expenses, where they can have the highest patient impact. AAP interventions can be wide-ranging, from direct patient support to broader activities that improve the health care system more generally. AAPs often leverage more than one strategy to remove barriers to access and affordability of medicines and support the delivery of health care to maximise the impact on patients who most need it.

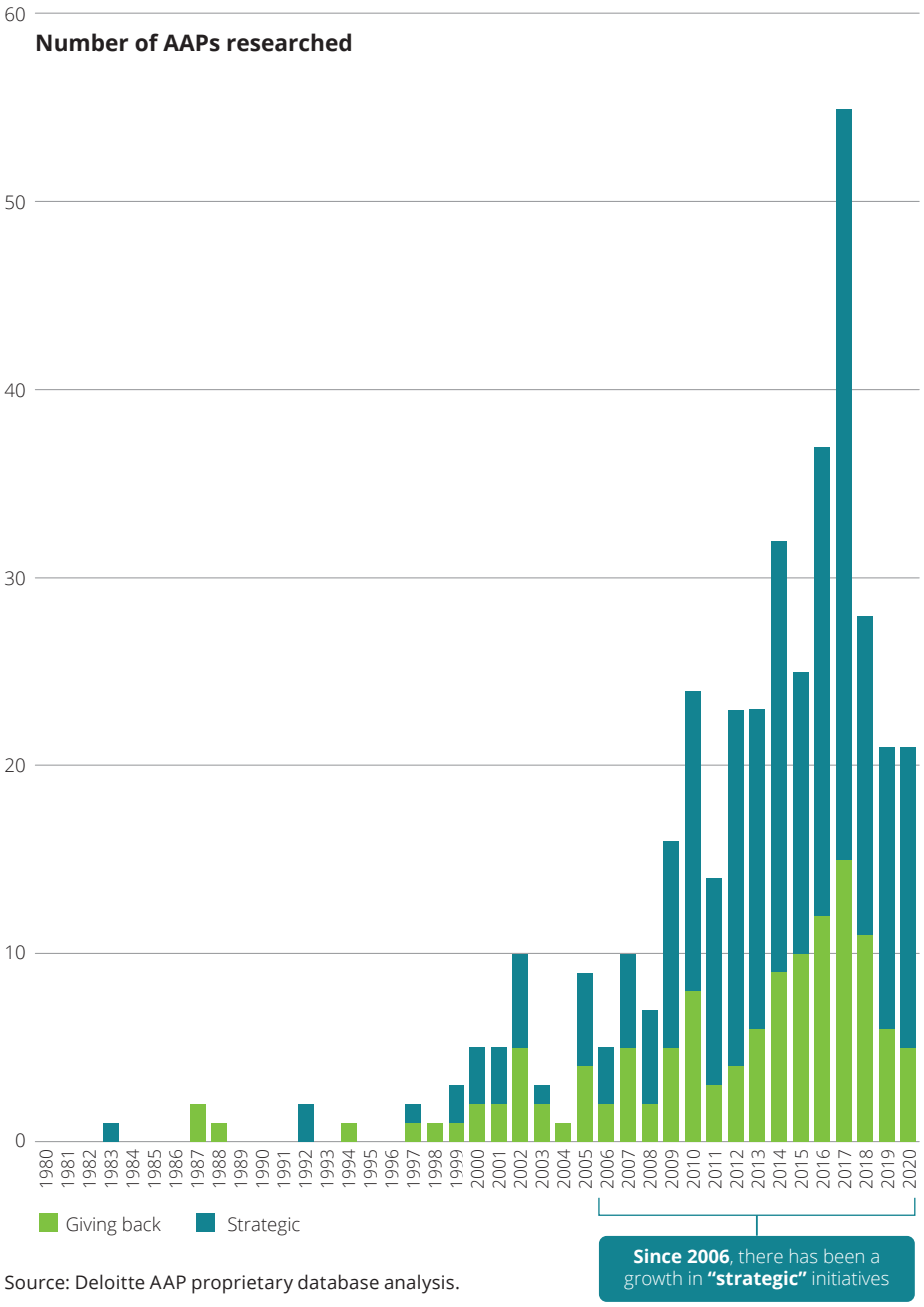
The importance of AAPs in pharma commercial strategy

The growing challenge of access to affordable medicines and the increasing commitments within the pharma industry to sustainability and social responsibility are driving the expansion of AAPs worldwide, in both volume and scope. In recent times, there has been a shift from AAPs targeted primarily at **giving back,** to those with a more **strategic** vision (**Figure 2** and **Figure 3**). Programmes that are aligned with a pharma company's commercial strategy can be used to create a competitive advantage, as opposed to being solely a charitable endeavour.

Figure 2. AAPs can be characterised by their vision type

Source: Deloitte analysis.

Figure 3. Number of AAPs initiated since 1980 by vision type



Source: Deloitte AAP proprietary database analysis.

Categorisation and mapping of AAPs

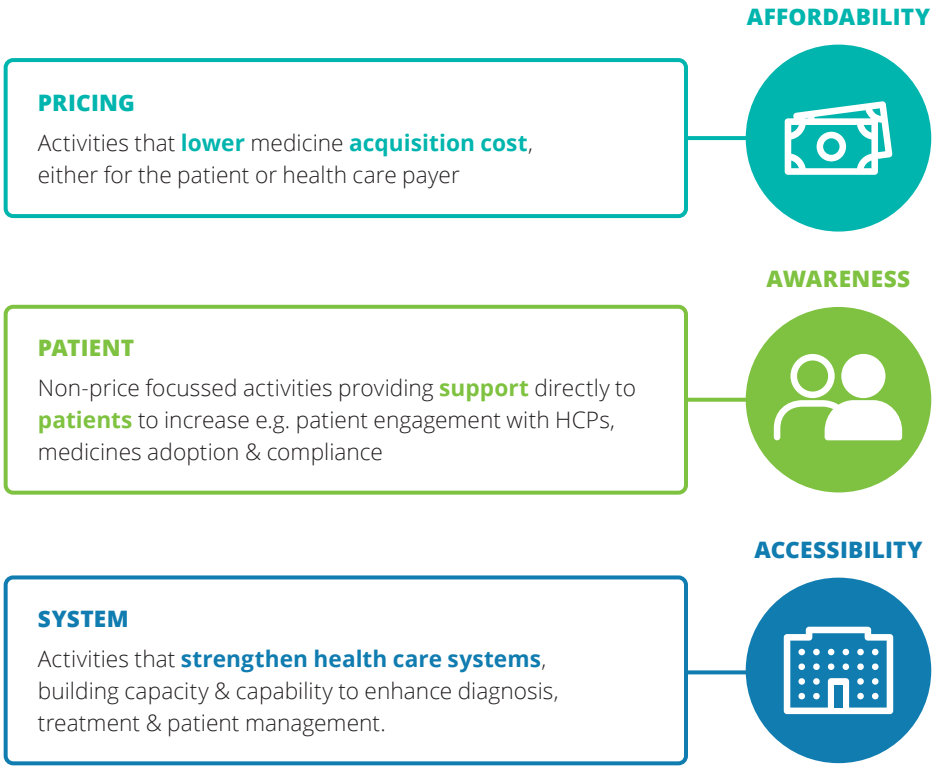
AAPs may need to overcome a number of different barriers to improving patient access to life-saving and/or life-extending drugs, and these programmes therefore vary hugely across markets, health care systems and therapy areas.

Despite the differences in barriers to access in each market, health care system or therapy area, AAPs are designed largely to target at least one of the following barriers:

- Affordability – AAPs focused on **price**
- Awareness – AAPs that support the **patient** holistically
- Accessibility – AAPs focused on improving access to quality **health care systems.**

Depending on their main focus, AAPs can be grouped into these three categories: those associated with the price (affordability); the patient (awareness); and the health care system (accessibility) (**Figure 4**).

Figure 4. Three categories of AAPs



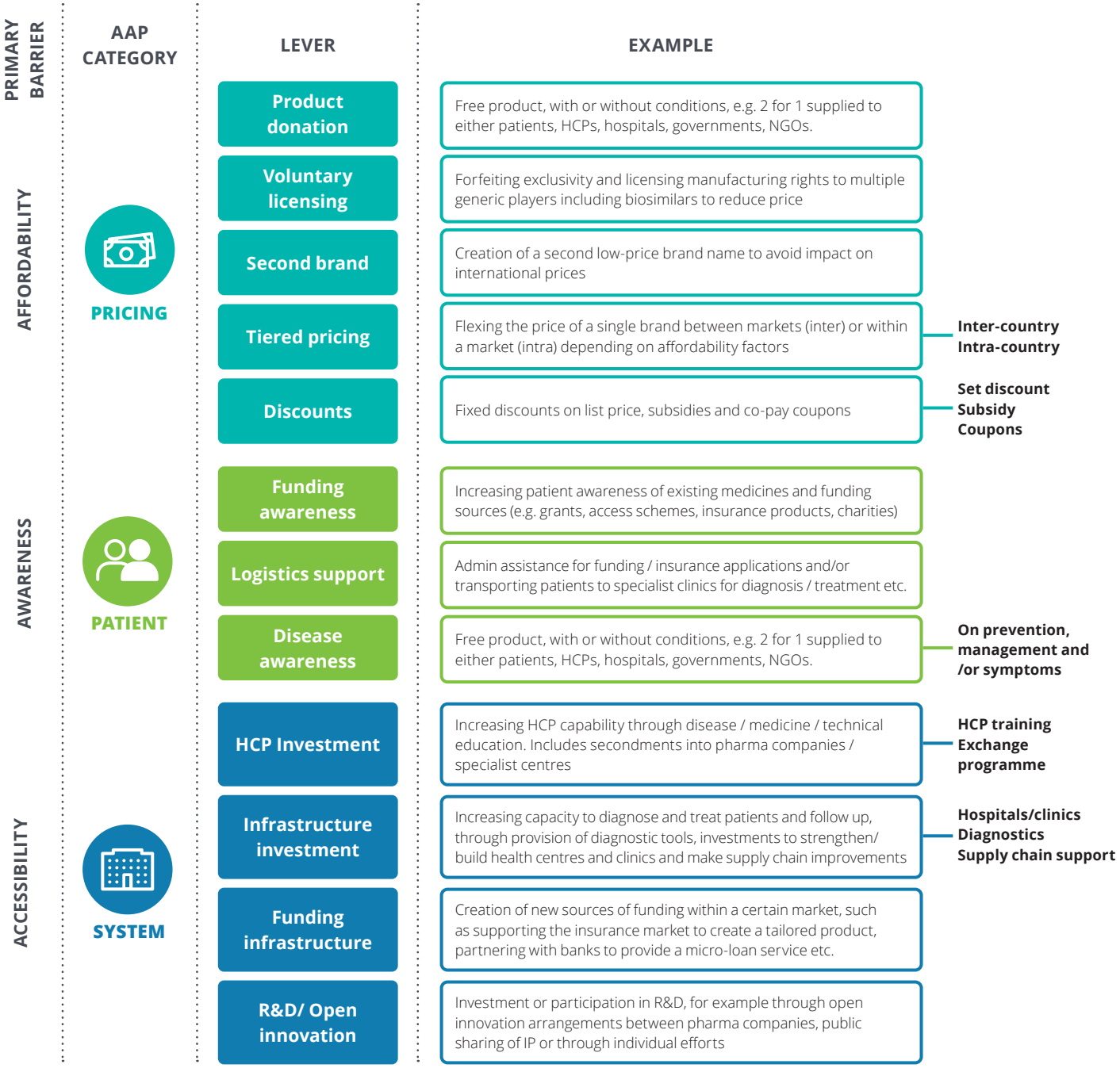
Source: Deloitte analysis.

> “Across the three AAP categories, a wide range of activities, or levers, are employed, with the ultimate goal of improving patient health and achieving universal access.”

Multiple levers to support access to medicines

Across the three AAP categories, a wide range of activities, or levers, are employed, with the ultimate goal of improving patient health and achieving universal access. The 12 levers listed in Figure 5 are commonly used by pharma companies.

Figure 5. The 12 levers typically employed by pharma companies across AAP categories



Source: Deloitte analysis.

The Deloitte Access and Affordability Programme database

Based on our experience in supporting pharma organisations, Deloitte has built a proprietary database of AAP programmes from across the world. This resource helps us to understand how organisations are helping patients to access the treatments they need. It provides insights into geographical determinants, therapy area nuances and how current ecosystem changes are shaping AAP strategies.

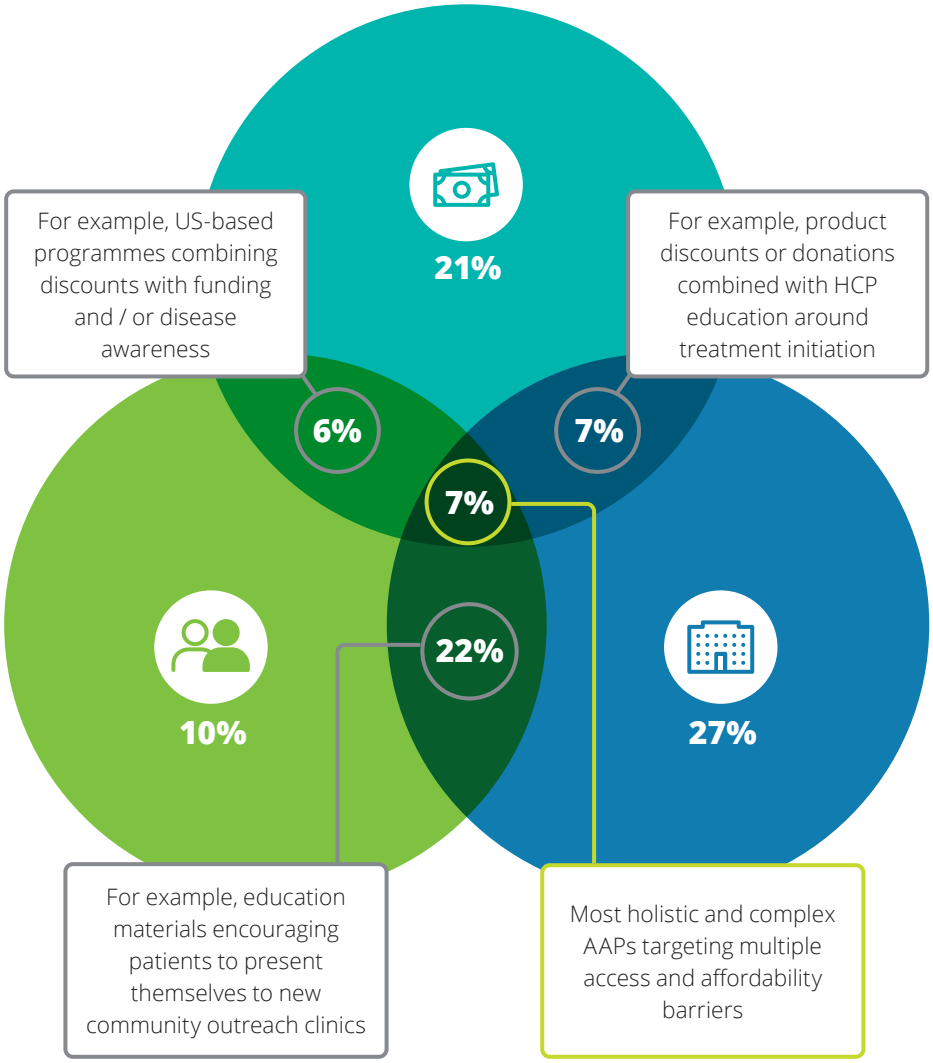
The AAP database includes:

- 400 AAPs from 24 pharma companies globally (including the top 10 largest pharmaceutical companies), covering patient, price and system activities
- 20 different therapy areas, including oncology, infectious diseases, metabolic disorders and cardiovascular disease
- Key programme details, including collaborations and partnerships, geography, programme start date and status.

The reality of AAPs: A hybrid model

In reality, many APPs combine multiple activities in a single initiative to target several affordability and access barriers at once. This is a more holistic approach to addressing patient needs. Our AAP database insights reveal that a purely system-focused AAP (accesibility) is the most common archetype, closely followed by a hybrid model comprising both patient- and system-focused interventions.

Figure 6. The hybrid AAP model – AAP archetypes as a percentage of AAPs researched



Source: Deloitte AAP proprietary database analysis.

Designing effective solutions

When designing successful AAPs that lower barriers and widen patient access to treatments, organisations need to take a holistic approach and consider different factors and potential ramifications across markets and therapy areas.

Market nuances based on patient out-of-pocket expenses

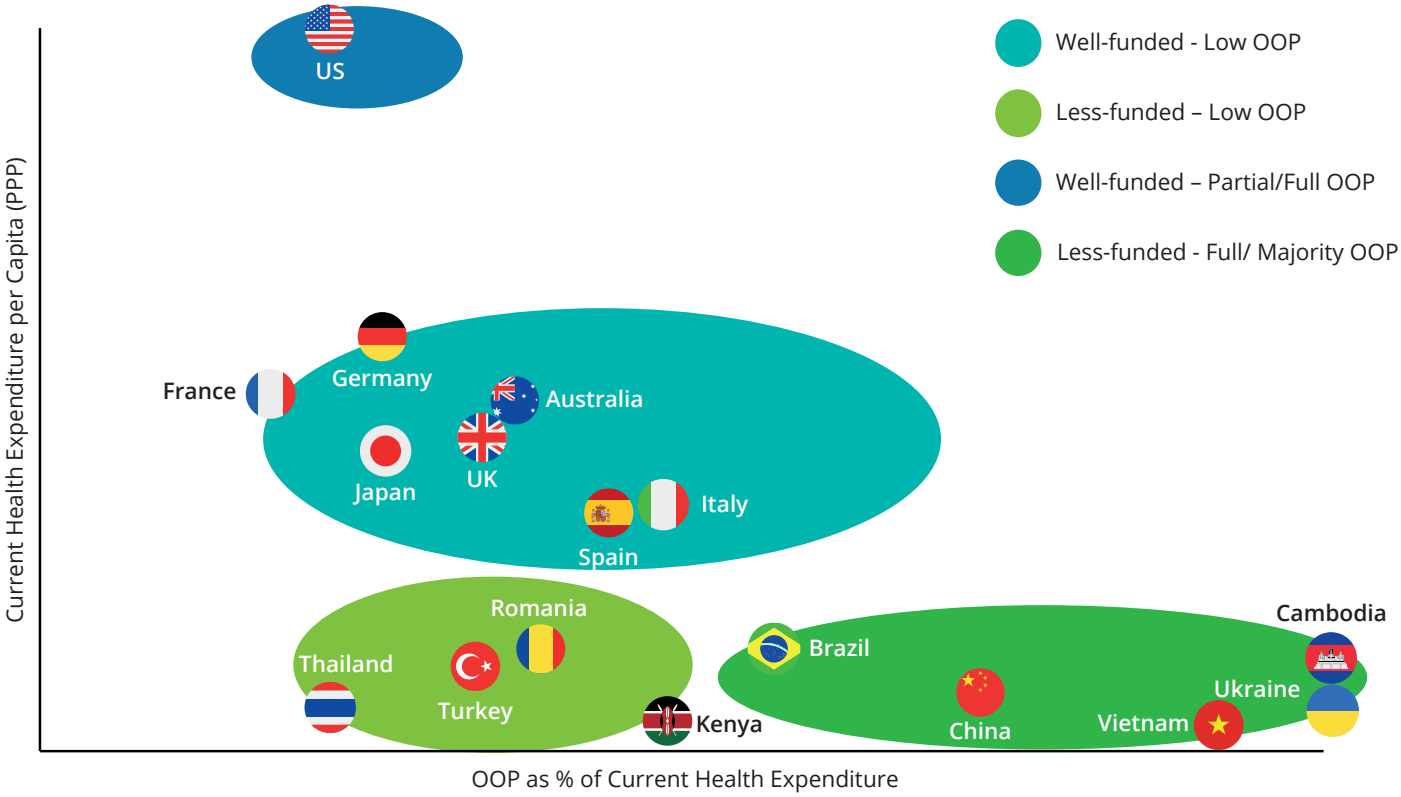
Patient access to medicines and health care is driven largely by how well-funded the health care system is, the level of disease awareness and education of the community, as well as the extent to which patients need to bear the financial cost themselves. When designing AAPs, pharma companies must consider the markets they are intended for, and the challenges facing patients within them. Medicine affordability is a significant issue globally, particularly where patients are expected to pay for their treatment out of their own pocket (OOP) (**Figure 7**).

We have identified four patient access archetypes that should be considered in the design of AAP to improve affordability and access. These range from full OOP payments to complete reimbursements where the patient does not pay anything (**Figure 8**).

Market nuances based on therapy areas

Alongside considerations of the local market, AAP design should be based on the varying challenges to access that arise within specific therapy or disease areas. For example, non-communicable diseases (NCD) accounted for 74 per cent of deaths in 2019 globally, with ischaemic heart disease as the most common cause of death.

Figure 7. Reliance on OOP expenditure: patient access archetypes



Source: WHO statistics[7]

The management of chronic diseases, such as diabetes and heart disease, is costly and requires active patient engagement for positive outcomes.

Cardiovascular disease can be managed with timely intervention and appropriate treatment. However, many patients lack access to effective disease management tools and therapies, particularly those in LMICs where health care systems are mainly directed towards acute care. AAPs that focus on the education and training of health care professionals (HCPs), promote diagnosis and provide health careinfrastructure investment help to support the health care system and improve access to diagnosis and treatment of cardiovascular disease, as well as other chronic diseases.

Oncology is another therapy area with a significant burden worlwide. The incidence of cancer is rising globally, and there is a need for health systems to improve the delivery of care to improve outcomes for patients. Cancer treatment and rehabilitation can be a lengthy process involving a wide range of health services, and health care systems need to be well managed to support oncology patients throughout their care. Many general cancer-orientated AAPs focus on reducing system-related barriers to the access of quality cancer care, including: improving diagnostic and screening capabilities; increasing HCP awareness and education; and investment into oncology clinics with specialist staff. However, affordability is also a key barrier in this therapy area due to the high costs of treatment, and pharma companies are also targeting their AAPs towards overcoming affordability barriers in order to make their oncology treatments more widely accessible.

Figure 8. Patient access archetypes to guide AAP design

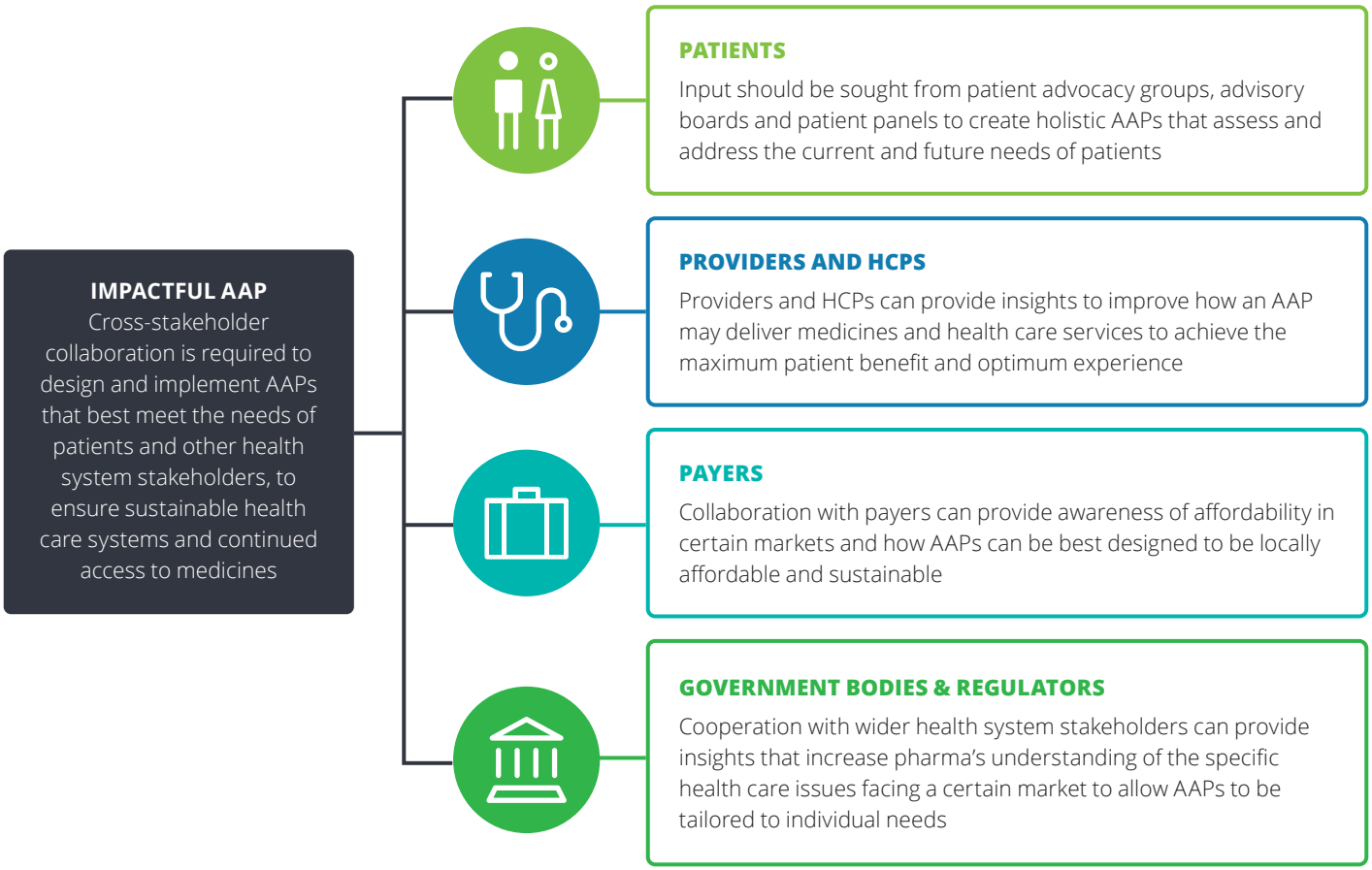
PATIENT ACCESS ARCHETYPES	AAP DESIGN CONSIDERATIONS
WELL-FUNDED - LOW OOP • Costs mostly reimbursed. Patients do not incur OOP costs or co-paying is capped for treatments • Well-funded health care system • e.g. UK, France, Italy, Japan	Well funded health systems with low OOP payments are most common in high-income European countries, where affordability may mainly be a challenge for advanced treatments such as cell and gene therapies. These are not typical markets for holistic AAPs, as innovative contracting and managed access agreements tend to be used to support payers (rather than patients). Affordability and patient adherence programmes, and more recently pathway support, are common for chronic illnesses such as diabetes.
LESS-FUNDED – LOW OOP • Mostly reimbursed, with a practice of informal payments • health care system is under-funded, may not be able to provide quality care and may lack resources for treatment & diagnosis • e.g. Romania, Thailand	Patients within these markets may be supported by insurance; however the health systems lack the resources and capabilities to provide high quality care. System focused AAPs can provide impactful change through investments in infrastructure and education of HCPs.
WELL-FUNDED – PARTIAL/FULL OOP • Partial co-pay/reimbursement and mostly OOP for newer medical treatments or therapy areas • Well-funded health care system • e.g. USA	Although health care systems and infrastructure in these markets may be mature and well funded, treatment affordability may not be. Insurance companies will often support basic treatments, and AAPs may enable access to innovative therapies, for example in oncology. Patient education and support for accessing funding programmes is critical in these markets.
LESS-FUNDED – FULL/MAJORITY OOP • Low or no reimbursement meaning patients mostly pay OOP • health care system is under-funded, may not be able to provide quality care and may lack resources for treatment and diagnosis • e.g. Ukraine, Vietnam, Brazil	Developing markets that are underfunded with a high OOP expense rely on holistic AAPs to overcome significant barriers to accessing medicines and health care. In these markets, donations, voluntary licensing and secondary brands become essential. Alongside affordability, should find new ways to support improvements in infrastructure and in building local capability such as education and upskilling from more mature markets.

Source: Deloitte analysis.

Cross-stakeholder input in AAP design

Cross-stakeholder engagement is critical in the design of a successful AAP. Collaborative input from various stakeholders, including patients, HCPs, payers, regulators and government bodies can help a pharma company recognise the priorities and to decide the focus areas for their AAPs. Insights from stakeholder engagement and collaborations can be used to design AAPs that will have the most impact in meeting the needs of patients and stakeholders across the health care system.

Figure 9. Collaborative working can help design effective AAPs



Source: Deloitte analysis.

> "Insights from stakeholder engagement and collaborations can be used to design AAPs that will have the most impact in meeting the needs of patients and stakeholders across the health care system."

How AAPs are evolving

Disruptive forces across health care and life sciences are transforming the industry dynamics and driving the emergence of more holistic and digitally-enabled AAP strategies.

Key industry trends and the impact on AAP strategies

Many health care and life sciences industry trends have re-shaped the health ecosystem in recent years, such as digital transformation of organisations and a shift towards value-based care models (**Figure 10**).

Figure 10. Impact of health care and life sciences trends on AAP strategies

		IMPACT ON AAP STRATEGIES
NEW PLAYERS AND PARTNERSHIPS	• New **disruptive entrants** and **partnerships** • **New cross-industry partnerships** created to support response	AAPs that leverage partnerships across the health care ecosystem are increasingly important. These may be with digital health or new health providers, employers, insurance, public health partners or patient organisations
INNOVATION CHARACTERISTICS	• Accelerating rate of **innovative and disruptive technologies**, with industry and regulators needing to keep pace • Reprioritisation of other assessments based on unmet need and **shifting regulator attitudes**	For innovative medicines, access considerations that need to be built into AAPs may include engagement with regulators to help new therapies reach patients faster and working with insurance companies to create new value models to make prices accessible to patients
FROM HEALTH CARE TO HEALTH	• Shift to **preventative and curative** approach, away from disease modification symptom management • Gene therapy / curative medicines with **significant budgetary and supply chain implication**	Advanced treatments mean higher costs that need to be addressed to ensure affordability. Patients are often involved throughout the product life cyle (e.g. cell and gene therapy manufacturing), whereby support and education throughout this complex journey is essential
VALUE-BASED HEALTH CARE	• Demand for **system value**, rather than stakeholder value / volume • **Sustainability issues** focusing payer attention on value maximisation	Value-based health care (VBHC) include the use of innovative contracting, is becoming central to access in many payer markets. There are many past lessons from AAPs that can be used to develop VBHC offerings across all market types
DATA ANALYTICS & INSIGHTS	• Emphasis on other data sources such as **real-world evidence (RWE) and patient-owned data** as well as **linked health care datasets** • **Live demonstration of true value of real time data** for tracking population health	Pharma companies should consider how data can be collected through AAPs, and insights applied throughout the patient journey. Programmes that do this well can support personalisation and adherence, and achieve improved outcomes
PATIENT ENGAGEMENT	• Engaged **consumers interested in personalised, patient centred** positioning and in disease prevention • Population **more engaged with their own health and supported throughout the patient journey**	The patient voice is more important than ever. Patients as consumers want to be engaged and informed throughout their treatment journey. Pharma companies must also think about patient needs holistically in their AAP design, for example recognising the criticality of mental health to adherence and improved patient outcomes

Source: Deloitte analysis.

AAPs becoming more holistic

Since 2010, the number of new AAPs has more than doubled, with programmes targeting multiple barriers to access and affordability within one single initiative (**Figure 11**). This holistic approach to the access and affordability of medicines and health care provides more areas of support for patients. Whilst the initial costs of designing holistic AAPs may be greater, their ability to extend product reach and target a wider range of patients more successfully may mean that the long-term impacts for patients may be greater.

Partnerships are becoming increasingly important

Cross-pharma public collaborations (e.g. governments, NGOs, global health agencies) are becoming increasingly important to help facilitate the concentrated efforts of multiple organisations within a single AAP. A collaborative approach can improve AAP effectiveness through combining the expertise of different organisations and extending outreach to a larger patient population.

For example, the Novartis Foundation launched the 'Better Hearts Better Cities' initiative to improve cardiovascular health in low-income urban communities by working with local authorities and partners from different sectors, including healthcare providers, digital technology companies, food suppliers, insurance funds, social enterprises and civil societies.[8]

Digitally-enabled AAPs

The adoption of technology is advancing at a rapid pace, which has been further accelerated by the COVID-19 pandemic. Embedded technology within the health care ecosystem helps to create stronger, more resilient health care systems for supporting patients, particularly in remote locations.

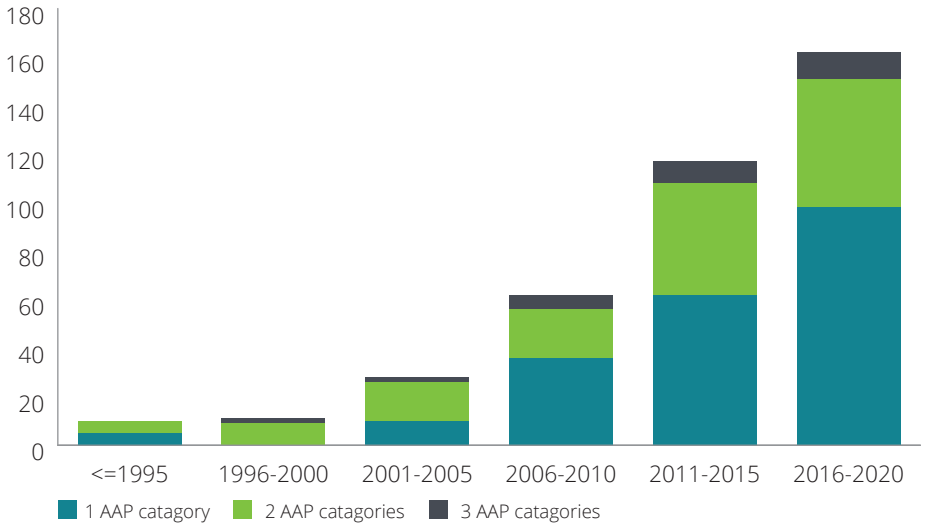
Health care AAPs are increasingly utilising tech-led solutions to provide access and support to patients (**Figure 12**). Utilising advanced technology within AAPs helps to improve the accuracyand efficiency of programmes and improve access and affordability for patients.

Of the AAPs identified in 2020, around 19 per cent have used some form of digital technology.

Digital technology can be utilised across all three key AAP categories to support patient access to medicines and health care. Examples include:

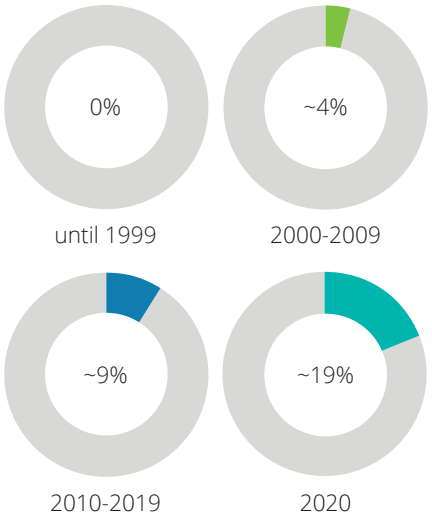
- HCP training though e-learning programmes
- Smartphone apps to monitor symptoms and alerts to improve adherence
- Tech-led drug discovery platforms
- AI-incorporated diagnostic tools
- Telehealth advice and support programmes
- Use of IoT technology and big data to improve patient experience
- Tech-led financial support programmes/ apps.

Figure 11. AAPs evolving in scope and complexity



Note: categories are affordability, awareness, and accessibility.
Source: Deloitte AAP proprietary database analysis.

Figure 12. Use of digital tools in new AAPs



Source: Deloitte AAP proprietary database analysis.

Focus increasingly on prevention of disease and early intervention

In alignment with industry trends, and the changing focus from 'delivering health care' to 'maintaining health', more AAPs are utilising diagnostic tools and screening methods to support prevention and earlier diagnosis of disease. Over the past decade, approximately 23 per cent of AAPs focused on supporting the diagnosis of disease in order to improve outcomes through activities, such as: initiating screening clinics; improving access to diagnostic tools; increasing diagnostic capacity in health care systems; and setting up patient engagement programmes to encourage presentation to clinics.

Early detection of disease enables earlier intervention and generally results in a better prognosis and quality of life for the patient, as well as reducing health care costs. An appropriate application of diagnostic tools facilitates early intervention and enables more effective and timely decision making for patients and clinicians.

COVID-19 has meant that many patients have missed screenings and follow-up appointments, which has had a damaging impact on the number of missed diagnoses, particularly in oncology. Pharma companies should engage with patients through AAPs to increase awareness and education of diseases that have minimal symptoms and often go undetected, and encourage patients to reach out to HCPs if they have concerns.

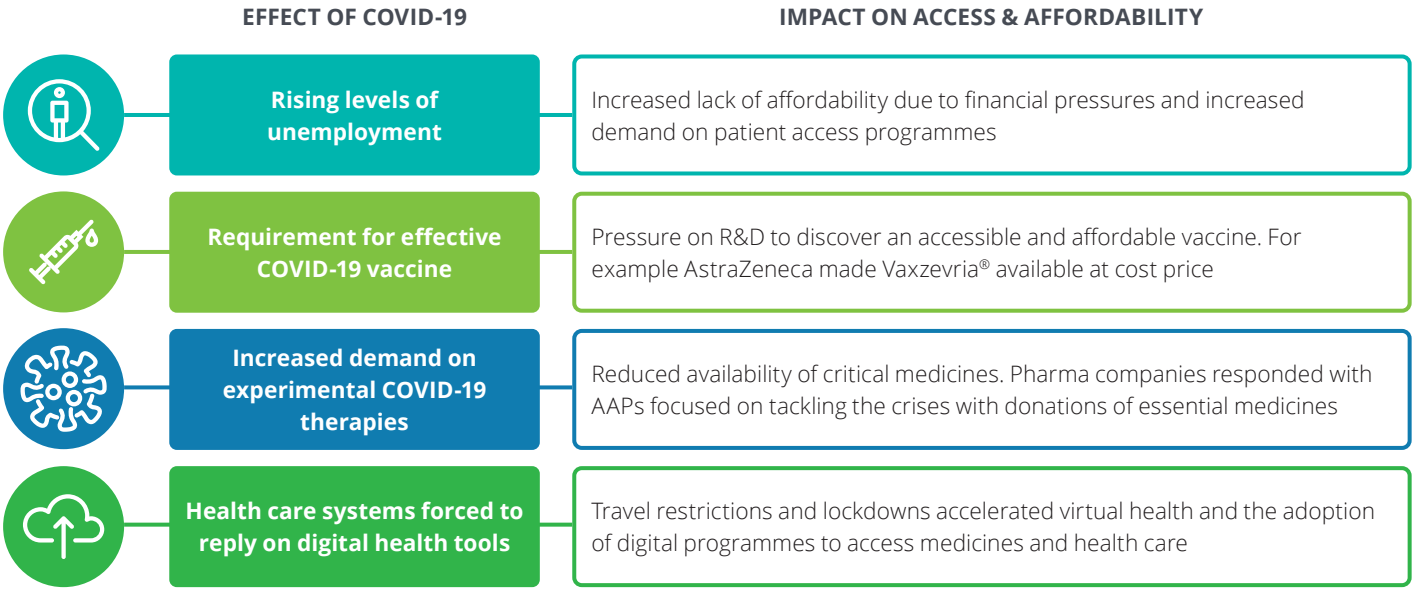
Prevention is even more effective than early detection. Embedding prevention within care and treatment pathways is the most effective way to avoid the burden of disease and associated health care costs. Whilst not yet practicable for all diseases, identifying those who are most at risk of developing a particular disease (or diseases), and modifying behaviour or using preventative medicines should become a key focus for AAPs through the use of data analytics.

The impact of COVID-19 has impacted on AAPs

The COVID-19 pandemic has highlighted and amplified many health care issues in an unprecedented way, by creating or exposing weaknesses in health care systems, disrupting supply chains, stretching health care budgets and exacerbating pre-existing inequities in access to medicines and health care around the world.

During the course of 2020, pharma companies were forced to switch resources from their planned annual strategies and deploy them in unexpected areas to respond to the pandemic. Pharma companies responded by focusing AAPs on help supporting health care systems and on activities to ensure continuity in medicine supply to patients (**Figure 13**). Some organisations adjusted pre-existing or new programmes to meet local needs that were particularly impacted by the pandemic.

Figure 13. Impact of COVID-19 on access and affordability



Source: Deloitte analysis from stakeholder interviews.

The future of AAPs

As challenges with access to affordable medicines and health care persist, AAPs need to adapt and support patients where they need it most.

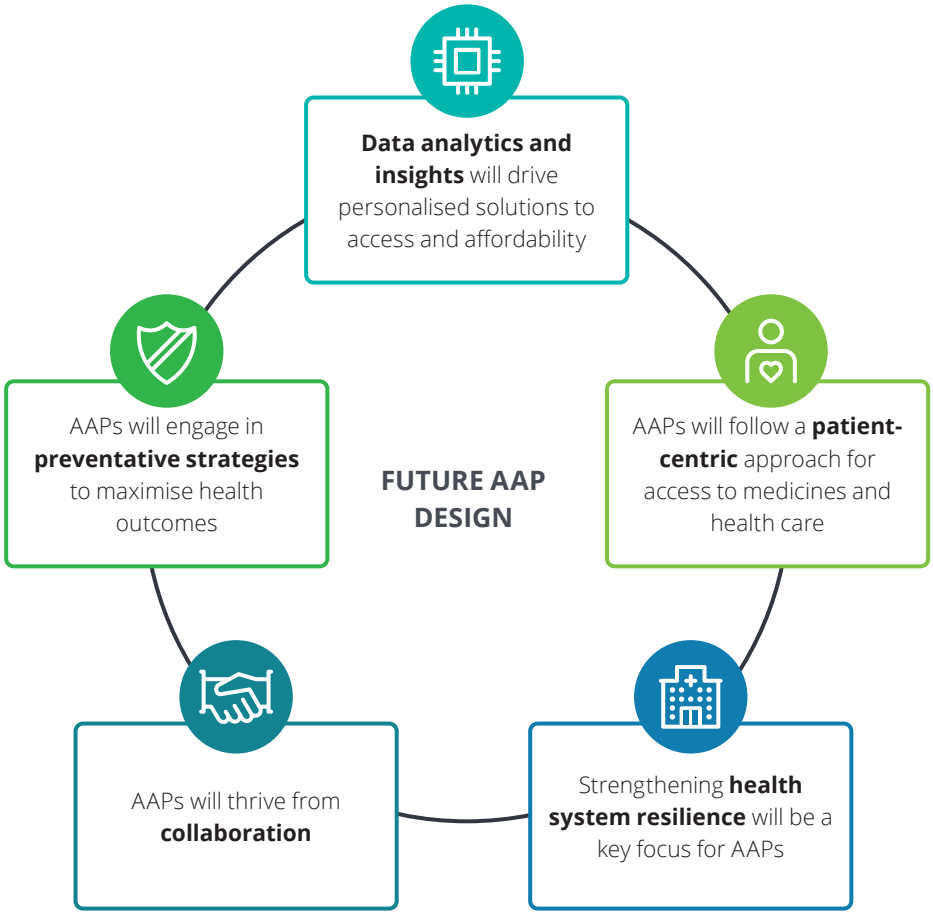
Based on our experience and insights our the AAP database, we envisage that, over the next five to ten years, innovation in AAP design will be essential to help pharmas keep pace with industry trends and changes within the health care ecosystem (**Figure 14**).

Data analytics: driving personalised solutions to access and affordability

In the future, we expect digital health technologies to be fully integrated into AAP design to deliver integrated end-to-end support across markets. The adoption of digital solutions will be welcomed in emerging markets as technology becomes more widely available, and health outcomes will improve as innovative tools are used to support adherence and disease management.

Health apps with the ability to collect real-world evidence (RWE) will enable the personalisation of treatment options and patient support. Linking RWE and health care outcomes data can support the implementation of value-based pricing models and innovative contracting that will, in turn, improve access and affordability. Sophisticated data analytics capabilities, including artificial intelligence (AI), that can make sense of the data flow will also play a key role in optimising AAP design.

Figure 14. Predictions for the future design of AAPs



Source: Deloitte analysis.

> “Linking RWE and health care outcomes data can support the implementation of value-based pricing models and innovative contracting that will, in turn, improve access and affordability.”

A patient-centric approach to access to medicines and health care

The transition to a patient-centred health care model will put patients' needs at the core of AAP design. Initiatives will provide support for patients throughout their care and be responsive to changes in the individual's circumstance. Data-guided insights will help to deliver this personalised approach and ensure AAPs target the specific barriers to access and the needs of a particular patient group within the local health system. Where regulation allows, AAPs will also provide a platform for pharma companies to engage with patients at a personal level, and form relationships that generate trust and improve adherence and outcomes.

Well-designed AAPs will support patient involvement in decisions about their care and HCPs will use digital tools to personalise and co-develop treatment plans with patients. Scientific advances including companion diagnostics will be adopted to tailor medicines further to individual needs and provide cost-effective solutions to treatment. A patient-centric approach to access to medicines and health care will motivate empowered patients to be actively involved in their own health care. AAPs will also help to address various barriers encountered by patients and provide easier access to care for an improved patient experience.

Strengthening health system resilience

A resilient health system is crucial for achieving a sustainable future with continued access to medicines and care. A lesson from the challenges to access created or exacerbated by COVID-19 is that in the future AAPs must be agile in responding to new barriers that arise and focus increasingly on preparing health care systems for future disease outbreaks.

A robust health information system is fundamental to a resilient health system. AAPs will need to support the adoption of advanced technology by adequatelly trained HCPs, particularly in emerging markets, to enhance readiness to respond to a crisis. Importantly, capacity building interventions within AAPs will also be key to ensuring that health care systems respond quickly and efficiently whilst maintaining their core functions.

Thriving from collaboration

COVID-19 has highlighted the importance of collaboration through partnerships to accelerate access to medicine and health care. We expect this trend to influence AAP design in the future, whereby pharma companies will engage increasingly with stakeholders across the ecosystem, to structure AAPs around cross-functional partnerships. Collaborative working with cross-industry experts will accelerate innovation within AAPs (e.g. through partnerships with AI or digital health companies). Co-operative efforts will also continue to increase the ability of AAPs to improve access and affordability.

AAPs will engage in preventative strategies to maximise health outcomes

Health care will increasingly focus on supporting underfunded health care systems in prevention and early intervention. Patients will become better informed about diseases they are at risk of, and have better understanding of preventative measures and identifying symptoms when they arise. AAPs will engage patients in a proactive way, and increasingly will be centred around preventative strategies and early diagnosis to maximise health outcomes.

Deloitte's view

The challenge of providing access to medicines and health care is now more pervasive than ever, and it will continue to increase as more life-saving and life-changing therapies come to market with price tags that render them out of reach for many people. The focus on health equity and sustainable access will also continue to be front and centre across the health care ecosystem, and pharma companies will need to respond in order to stay relevant and build trust. Designing and delivering diverse, holistic and well-thought-out AAPs will be critical to achieving this and pharma should pursue strategies with this vision of the future in mind.

Glossary

AAP	Access and affordability progamme
AI	Artificial intelligence
HCP	Health care professional
IoT	Internet of things
LMIC	Low-to-middle-income country
LIC	Low-income country
NCD	Non-communicable disease
NGO	Non-governmental organization
OOP	out-of-pocket
Pharma	Pharmaceutical
RWE	Real-world evidence
VBHC	Value-based health care
WHO	World Health Organization

Endnotes

1. WHO, "Access to Medicines, making market forces serve the poor", 2017, accessed 28 May, 2021.

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Authors

Elizabeth Hampson
Director
Deloitte MCS Ltd
+44 (0) 20 7007 8169
ehampson@deloitte.co.uk

Victoria Katzer
Consultant
Deloitte MCS Ltd
+44 20 7303 7847
vkatzer@deloitte.co.uk

Sophia Davison
Manager
Deloitte MCS Ltd
+44 (0) 20 7007 0190
sophiadavison@deloitte.co.uk

Oliver Whight
Senior Manager
Deloitte MCS Ltd
+44 (0) 20 7007 2492
owhight@deloitte.co.uk

Maria João Cruz
Senior Consultant
Deloitte MCS Ltd
+44 (0) 20 7303 4434
mariajoaocruz@deloitte.co.uk

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Contacts

James Gregson
Partner, Life Sciences and Healthcare Industry Lead
Deloitte MCS Ltd
+44 (0) 20 7007 8866
jgregson@deloitte.co.uk

Hanno Ronte
Partner, Life Science & Healthcare
Deloitte MCS Ltd
+44 (0) 20 7007 2540
hronte@deloitte.co.uk

Gregory Reh
Deloitte Global Life Sciences & Healthcare Industry Leader
+1 (215) 997 7559
grreh@deloitte.com

John Haughey
Deloitte Global Life Sciences & Healthcare Industry Consulting Leader
+44 (0) 20 7303 7472
jhaughey@deloitte.co.uk

Vicky Levy
Deloitte Global Life Sciences Sector Leader
+1 (617) 437 3325
vlevy@deloitte.com

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