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Opportunities for Accelerating AIDS Vaccine R&D in China

China has made significant commitments to controlling its AIDS epidemic, making large investments in prevention and treatment programs. It also has signaled a determination to invigorate its life sciences research and development (R&D) capabilities to become a global innovator in the biopharmaceutical sector. In this time of rapid growth and scientific progress, China is poised to assume greater leadership in one of the most important intersections of public health and innovation: the development of a vaccine to prevent HIV infection.

As an essential part of its mission, the International AIDS Vaccine Initiative (IAVI) works with countries with emerging scientific capacity, such as China, to help strengthen their capabilities in biopharmaceutical innovation and help them to become more actively engaged in AIDS vaccine design and development. To that end, IAVI consulted with the Department of Medical Sciences, Technology and Education of China's Ministry of Health to examine the policy environment for AIDS vaccine R&D in the country and identify policies that could bolster China's efforts in that field of research. We commissioned McKinsey & Company to conduct this research, which involved literature reviews, interviews and focus groups with thought leaders from the Chinese government, private industry, academia and civil society. The observations and recommendations included here are based on McKinsey & Co.'s report "Accelerating AIDS Vaccine Development in China: Challenges and Opportunities" (McKinsey, 2010).

Promise of an AIDS Vaccine for China and the World

Although HIV prevalence in China is relatively low at around 0.05%, AIDS remains a serious threat to Chinese public

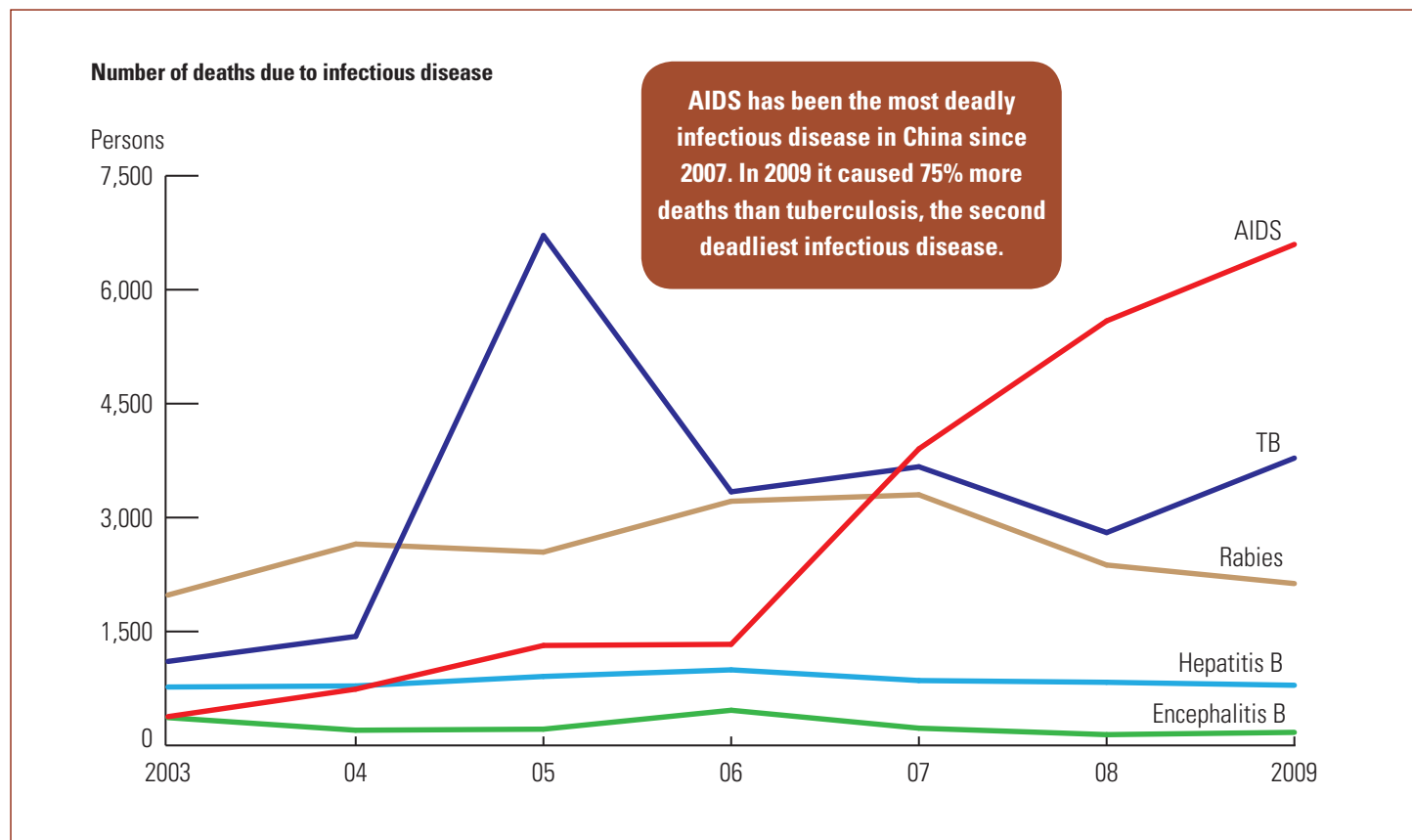
Overview of Policy Recommendations for Accelerating AIDS Vaccine R&D in China

- Sustain and target government financing and incentivize private investment
- Strengthen research networks and build links with efforts in other disease areas
- Improve the regulatory and IP environment to decrease investment risk

health, economic development and social stability. China currently accounts for 2% of all global HIV infections, and AIDS has become the leading cause of death by infectious disease in China (see Figure 1, next page). The predominant routes of HIV transmission in the country have changed over time: While HIV was historically transmitted primarily through drug use and blood transfusion, sexual transmission has spiked in recent years. The proportion of new infections acquired through heterosexual contact almost doubled between 2007 and 2009, and the proportion of new infections among men who have sex with men increased by a factor of 16. This dramatic shift suggests that the epidemic could be spreading to the general population, with serious implications for social stability and economic growth. In 2007, Chinese researchers projected that between 2006 and 2010 the nation's HIV epidemic would be responsible for a direct loss of US\$ 2.75 billion to the national economy, and that indirect losses associated with the epidemic could reach as high as \$50 billion (Li, 2007).

The Chinese government has rapidly escalated its HIV-prevention and treatment programs. Funding for HIV control

Figure 1: AIDS is the Most Fatal Infectious Disease in China



grew at an annual rate of roughly 120% from 2000 to 2004, and an additional ~5% each year between 2004 and 2009. China spent about \$300 million on HIV treatment and prevention in 2009. Though this is a significant step in the right direction, global analyses suggest that existing HIV-prevention strategies, even if scaled up to maximum levels, will be unable to reduce the number of new infections to levels required to control and ultimately end the pandemic (Hecht, 2010). New prevention technologies, including a vaccine, will be required to further reduce new infections and enable a sustainable treatment response. IAVI's analyses suggest that a vaccine that is 50% effective, given to 30% of the adult population in developing countries, could prevent 24% of new infections (5.6 million) over a 15-year period (IAVI, 2009). A preventive AIDS

vaccine could be a game-changing tool in the global campaign against HIV. It could control and eventually help to end the AIDS pandemic in China and around the globe.

Strengthening China's Capacity for Biopharmaceutical Innovation

China is investing heavily in science, technology and innovation to drive future economic growth. In 2006, its government released a strategy to advance the nation's capabilities in science and technology, with the aim of making China "an innovative nation in the next 15 years and a world power in science and technology fields by the middle of the twenty-first century" (State Council, 2006). In its latest five-year plan for economic and social development, covering 2011-2016, China aims to invest 2.2% of its gross

domestic product in R&D activities, up from 1.75% in 2010. The 2011 budget will see a 12.5% increase in science and technology funding over 2010 levels (Stone, 2011). A major cornerstone of this drive is a series of state funding initiatives, or "Mega Projects," to develop key technologies. Among other technologies, the Mega Projects seek to develop innovative drugs and vaccines, including an AIDS vaccine. In the 2011 budget, government funding for the Mega Projects is set to increase by 30% over 2010 levels. The budget for China's National Natural Sciences Foundation, the country's primary funder of basic science research, has also doubled over the past two years. This investment, if adequately applied to AIDS vaccine design and development, has the potential to contribute not only to the development of a game-changing tool to control

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China's HIV epidemic, but also to enhance the country's role in global health and development, particularly among low- and middle-income countries.

The Chinese AIDS Vaccine R&D Landscape

China has a dynamic AIDS vaccine research community, with at least seven groups conducting AIDS vaccine R&D projects. Two vaccine candidates are currently in human trials in China and others are at earlier stages of development. AIDS vaccine projects are mainly conducted by leading academic and government-affiliated research groups, with minimal participation from the biotechnology and pharmaceutical industries. Approximately 10% of the Chinese government's funding for AIDS control, estimated at just under \$15 million in 2009, supports AIDS vaccine design and development. This funding is expected to grow significantly in 2011 and beyond (HIV Vaccines and Microbicides Resource Tracking Working Group, 2010).

Obstacles to AIDS Vaccine Development in China

McKinsey & Co.'s research revealed three primary inhibitors of AIDS vaccine R&D in China. These include:

Investment and Incentive Issues:

While the Chinese government has significantly increased its investments in AIDS vaccine R&D in recent years, stakeholders suggested that funding is not targeted as effectively as it could be. Novel basic research on HIV and the translation of that research into AIDS vaccine candidates—known in the field as translational research—were cited as two key areas lacking sufficient government support. Interviewees noted that funds are concentrated among a small number of leading research groups, with little investment targeting smaller groups

employing new approaches, and that requests for proposals are not well disseminated beyond a small circle of established research groups. The concentrated nature of funding and barriers to entry may prevent young investigators and less well-known scientists from pursuing research relevant to AIDS vaccine design and may discourage scientists from taking high-risk, but potentially high-reward, approaches to solving the toughest problems of the field.

In China, as elsewhere, the scientific risks of AIDS vaccine R&D and uncertain commercial returns of a potential AIDS vaccine inhibit significant private-sector investment. Private biopharmaceutical firms, however, possess expertise essential to the development and deployment of AIDS vaccines. Any company's decision to invest in high-risk science depends on its perception of the potential commercial return from the endeavor. Factors that increase the uncertainty of commercial returns, including regulatory or intellectual property issues that adversely affect the size of future markets and the company's access to them, can diminish its appetite for upstream investment.

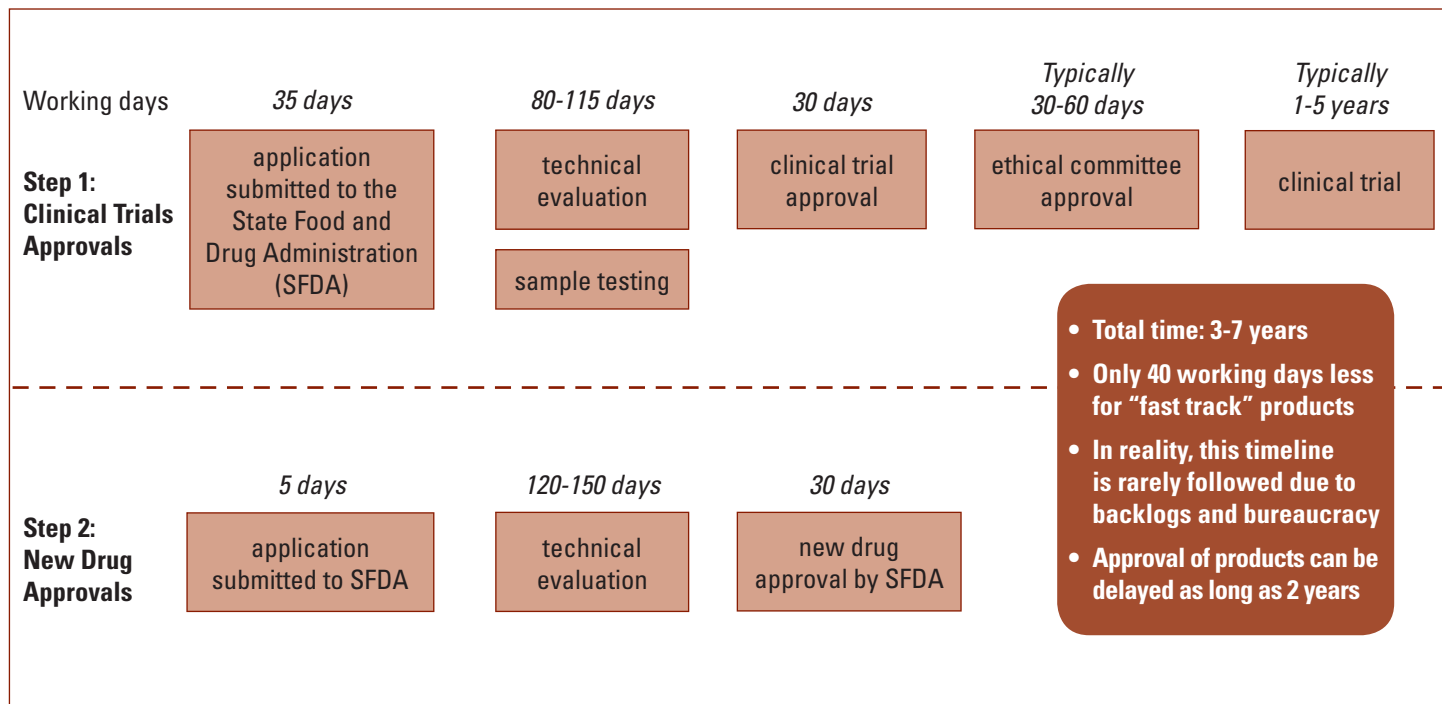
Collaboration and Coordination

Issues: Stakeholders also highlighted fragmentation as a factor inhibiting AIDS vaccine R&D. They noted that there is little collaboration or coordination of efforts between groups researching AIDS vaccines in Chinese universities, public institutes and private firms. Interviewees suggested that a lack of mechanisms in China to foster collaboration between researchers in different sectors and with scientists abroad stymies innovation and slows progress, particularly in translational research. Recent efforts in improving such collaboration, such as the formation of the China AIDS Vaccine Initiative (CAVI) and the regional AIDS Vaccine for Asia Network (AVAN) currently hosted by China, were widely acknowledged as exceptionally promising advances. But respondents said that additional and stronger mechanisms to encourage collaboration are needed. They also observed that researchers trying to develop vaccines against HIV in China tend to be isolated from similar efforts in other disease areas. Closer coordination and collaboration with researchers working on other diseases may generate new scientific insights and facilitate access to additional



Juliana Thomas Photography

Figure 2: Regulatory Processes May Slow Product Development



resources through cross-subsidization from investments into disease areas that are likely to be more profitable to the private sector.

Regulatory and Intellectual

Property Issues: China has recently taken significant steps to strengthen its regulatory and legal frameworks to facilitate scientific and technological innovation. For instance, its regulatory system for vaccines was recently reviewed and approved, or prequalified, by the World Health Organization, which will open the door for Chinese firms to export vaccines through multilateral channels. This increased certainty in the size of future export markets may be a powerful incentive for upstream investment in public health technologies, such as an AIDS vaccine. Despite these significant advances, stakeholders identified some notable remaining obstacles to innovation in China’s regulatory and legal environment. In the near term, these issues may limit opportunities to build scientific capacity and

discourage upstream investment. In the longer term, they may slow the development and eventual deployment of effective vaccines.

First, regulatory authorities require that drug and vaccine candidates that have been designed and developed abroad go through the entire process of clinical evaluation in human trials conducted in China, regardless of how extensively they have been evaluated in other countries. Respondents suggested that this may serve as a disincentive to international collaboration and investment, a pathway by which China can build its scientific knowledge and technical capacity.

Second, complex regulations governing scientific discovery and product development are perceived to slow progress. The regulatory review of study protocols and drug approvals is widely seen as being inefficient, often taking several years beyond the officially sanctioned three to seven years (see Figure 2, above). While

some products qualify for “fast track” approvals, stakeholders said that such a designation tends to reduce the approval timeline only by a few weeks, though there have been instances of much faster approval in public health emergencies. For example, when an outbreak of swine flu occurred in 2009, the government allowed companies to submit product registration applications concurrent with clinical trial activities, and synchronized government safety inspections with the companies’ quality-control procedures, in an approvals process that took just 87 days.

Third, stakeholders observed that the perception persists, both domestically and abroad, that China remains weak in protecting intellectual property rights and that some laws governing ownership of biopharmaceutical innovations are unclear. McKinsey & Co.’s analysis suggests that China’s application of its patent law in the life sciences sector has in fact been quite strong, particularly since it joined the

World Trade Organization in 2001. Further, laws delineating ownership and use of patented discoveries meet international standards.

Nevertheless, stakeholders noted that the widespread perception that the opposite is true increases uncertainty about the prospects of future commercial returns and so exacerbates the risk associated with investing in vaccine development. This too, they suggested, discourages researchers and companies from engaging in upstream HIV vaccine research.

Opportunities for Accelerating AIDS Vaccine R&D in China

McKinsey and Co.'s analysis culminated in a set of policy recommendations to strengthen the environment in China for biopharmaceutical innovation broadly, and for AIDS vaccine development specifically. These recommendations were vetted and refined through further discussion with Chinese stakeholders.

Recommendation 1: Sustain and Target Government Financing and Incentivize Private Investment

To accelerate progress in AIDS vaccine design and development, the Chinese government should continue to prioritize AIDS vaccine R&D in their expanding science and technology programs. Funding can also be better targeted to fill identified gaps and stimulate essential R&D activities, particularly risky but potentially innovative applied science and translational research. Government policies can also help attract additional resources, particularly from the private sector. Specific strategies to that end include:

- *Ensuring that AIDS vaccines and related scientific and technological platforms continue to be prioritized in China's 12th five-year plan and annual appropriations.*



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Disseminating new evidence of the potential public health and economic impact of future AIDS vaccines and other prevention technologies may be important to advocating for continued prioritization of AIDS vaccine development. For example, China's National Center for AIDS/STD Control and Prevention, in collaboration with IAVI and the Futures Institute, is modeling the potential public health impacts of a range of HIV control strategies, including an AIDS vaccine, in China.





- *Establishing Innovation Funds.* In addition to the Mega Projects, which were launched with the express purpose of bringing promising technologies to market, the Chinese government could establish funding mechanisms to encourage high-risk/high-reward approaches to AIDS vaccine design. The government could develop more transparent resource-allocation strategies to ensure funds reach less well-known groups, private companies, and junior researchers, in addition to high-profile research centers. Figure 3 (next page) shows some examples of such

funding programs. China does have an Innovation Fund for Small Technology-Based Firms, but this has not been applied to AIDS vaccine development. The fund could be expanded, or a similar fund established, to stimulate greater innovation in AIDS vaccine R&D.

- *Instituting incentive mechanisms to encourage private-sector participation and investment in AIDS vaccine R&D.* Successful examples of incentive mechanisms in other countries include:

- ◆ Programs that make direct government financing available to private companies, or partnerships between industry and academia, such as the US Small Business Innovation Research award, India's Small Business Innovation Research program and Brazil's Fund for Scientific and Technological Development
- ◆ Public-private partnerships that coordinate portfolios of R&D activities across sectors, assume investment risks and support translational research

Figure 3: Funds Designed to Stimulate Innovation

Institution & Fund	Fund Size/Duration	Objective	Examples of Innovations
 Grand Challenges Explorations	US\$ 100 mm over 5 years beginning in 2008 US\$ 100,000 for each successful application	Encourage researchers to explore early stage, transformational ideas that could change the face of health in the developing world	HIV testing in hair Diagnosing TB with an “electronic nose” Battling malaria using scorpion venom
  Health Innovation Challenge Fund	GBP £100 mm over 5 years beginning in 2010 Full economic costs calculated by applying universities will be covered once the universities are selected	Stimulate the creation of innovative healthcare products, technologies and interventions, and facilitate their development	Not applicable. Initiative in early stages.
 Innovation Fund	US\$ 10 mm over 4 years beginning in 2008, with half provided by BMGF	Encourage cross-pollination of ideas and technologies among scientific sub-disciplines Infuse creativity into the search for a safe and effective AIDS vaccine	Artificial immune system for screening vaccine candidates Novel neotope- and cryotope-based vaccine candidates

Innovation funds may engage new research teams with high-risk, high-reward ideas

Recommendation 2: Strengthen Research Networks and Build Links with Efforts in Other Disease Areas

The Chinese government can help ensure that recently developed networks to facilitate collaboration across the field of AIDS vaccine research, including CAVI and AVAN, continue to grow. This might involve supporting the expansion of these networks to include additional companies, research groups and international partners, and helping to build their capacity to provide value-added services such as centralized fund management and shared scientific platforms. In addition to strengthening collaboration and coordination within the AIDS vaccine development field, building links with

vaccine-development efforts in other disease areas may promote the cross-pollination of scientific advances and ensure that efforts are mutually reinforcing, potentially attracting new and larger investments. Specific strategies might include:

- *Establishing a global health vaccine research center to serve as a central hub across disease areas.* Such an institution could be a national center of excellence in vaccine discovery and preclinical development, facilitating collaboration between academia, public-private partnerships and international networks; establishing shared facilities and technological platforms; and attracting and managing new investments. While

respondents suggested that such an integrated center would have high impact on the field, no single existing institution was identified as having the capacity for such an undertaking. A new public-private partnership may have to be established, or an existing network expanded and empowered to coordinate institutions involved in global health vaccine science.

- *Creating integrated vaccine R&D platforms across disease areas, which could provide technology and expertise for pre-clinical assessment of vaccine candidates, production capacity for clinical trials and scale-up and quality assurance and control of vaccine products.* Such technological platforms could attract

Box 1: Japan Benefited from Accepting Foreign Clinical Trials Data on Foreign-Discovered Products

Prior to 1998, the Japanese government, like China's today, required foreign pharmaceutical firms to complete the full process of clinical trials in Japan, regardless of whether similar trials had been completed abroad. After six years of negotiations with foreign companies, Japan eliminated this requirement in 1998 to significant effect: Japanese people benefited from new drugs developed by international firms, foreign firms boosted employment in Japan and competition from multinational corporations led Japanese firms to accelerate R&D and develop better products.

investment from the private sector for commercially viable products, which could cross-subsidize R&D for less profitable products. The Chinese government has initiated development of shared technological platforms for vaccines and other technologies and is likely to further increase investment in this area under the 12th five-year plan. However, none of the existing or planned technological platforms has as broad a disease scope or as robust technological capabilities as is recommended here, and most focus on downstream vaccine production and commercialization. For example, the new National Engineering Research Center (NERC) for Novel Vaccines will feature technology platforms for downstream vaccine commercialization. But, so far, AIDS in general, and upstream R&D in particular, have been beyond the NERC's mandate.

Recommendation 3: Improve the Regulatory and IP Environment to Decrease Investment Risk

China's regulatory and intellectual property environment can be further strengthened to support the cultivation of scientific capacity, reduce the risk of investing in upstream R&D in the near term and, in the longer term, accelerate

the development and deployment of effective vaccines. Specific strategies China might pursue include:

- *Easing the requirement that drug and vaccine candidates developed abroad be re-tested from Phase I onward in China.* Other countries, including the U.S., have accepted data on products tested abroad while maintaining strict protections for their populations. Such measures will lower barriers to international collaboration and strengthen opportunities to build scientific capacity (see Box 1, above).
- *Implementing a more robust fast-track mechanism for the development and approval of products of importance to public health, such as AIDS vaccines.* This could reduce the risk and uncertainty created by lengthy and cumbersome regulatory processes and potentially incentivize greater upstream investment.
- *Reinforcing both government and private-sector understanding and commitments on IP-related issues to strengthen confidence among researchers, firms, funders and partners that intellectual property rights will be protected.* This may involve developing materials and holding workshops outlining the relevant laws,

processes and procedures for IP protection and enforcement in the Chinese system.

Conclusion

With an active AIDS vaccine research sector, demonstrated public commitment to AIDS control, significant and growing investment in science and technology and a rapidly expanding capacity for biopharmaceutical innovation, China is well positioned to assume greater leadership in AIDS vaccine development. While China is well on its way to becoming a global scientific power, targeted policy choices can boost biopharmaceutical innovation and harness these capabilities to drive AIDS vaccine development. Policies that may accelerate China's leadership in AIDS vaccine development include the following:

- Those that sustain public investments and target them to support innovative basic science and translational research
- Those that encourage additional investment by private industry
- Those that strengthen mechanisms for collaboration between researchers within the AIDS vaccine development field and with other disease areas
- Those that streamline regulatory processes and IP protections to reduce investment risk

While the purpose of such measures would be to ensure development of the global public good of an AIDS vaccine, these policy reforms and investments would likely contribute to China's overall capacity for biopharmaceutical innovation as well, enhancing its competitive advantage in this critical economic sector and its contributions to global public health and development.

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Insights

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