



China Country Profile

2023

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China has a robust national immunization program that is well funded by the national and provincial governments



Indicators	Status (2022)
Population	1.4B
Birth Cohort (M)	10.62M
Under 5 Mortality Rate (# per 1,000 live births)	7
EPI Coverage	<ul style="list-style-type: none"> • 95% for 12 EPI vaccines included for 11 VPDs • Hib, HPV, PCV, and Rota vaccines are currently Non-EPI vaccines which must be paid out of pocket
National EPI Manager	China CDC National Immunization Program
GNI per capita (USD)	\$12,850
Government Health Spend (% per GDP)	5.59% (2020)
Gavi Country Status (Y/N, Year of Transition)	No, with special Gavi support limited only to Hep B Vx (YE2002 - YE2011)
Contribution to Gavi	2016-2020: \$5M 2021: \$100M (Specifically for COVAX AMC) 2021-2025: \$20M
COVAX country (Y/N, Note)	Yes/Self-financing, but not procured via COVAX

China EPI vaccine coverage has been consistently above 96% across multiple vaccines, higher than most countries in the world



WHO vaccine-preventable diseases: monitoring system Global summary UNICEF estimates time series for China (CHN)

Vaccines	2022	2021	2020	2019	2018	2017	2016	2015	2014	2013	2012
BCG	99	99	99	99	99	99	99	99	99	99	99
DTP1	99	99	99	99	99	99	99	99	99	99	99
DTP3	99	99	99	99	99	99	99	99	99	99	99
HepB3	99	99	99	99	99	99	99	99	99	99	99
HepB_BD	95	95	95	96	96	96	96	96	94	99	96
Hib3		-	-	-	-	-	-	-	-	-	-
IPV1	99	99	99	99	99	99	-	-	-	-	-
MCV1	99	99	99	99	99	99	99	99	99	99	99
MCV2	99	99	99	98	99	99	99	99	99	99	99
PCV3		-	-	-	-	-	-	-	-	-	-
Pol3	99	99	99	99	99	99	99	99	99	99	99
RCV1	99	99	99	99	99	99	99	95	98	96	95
RotaC	-	-	-	-	-	-	-	-	-	-	-

China EPI includes 12 essential vaccines for 11 vaccine preventable diseases (VPDs) but has yet to introduce PCV, HPV and Rota



China EPI Vaccine Schedule (2022)

VPDs	Vaccine Type	Administration	Dosage	Age of vaccination															
				Birth	1M	2M	3M	4M	5M	6M	8M	9M	18M	2Y	3Y	4Y	5Y	6Y	
Hepatitis B	Hep B	Intramuscular	10 or 20µg	1D	2D						3D								
Tuberculosis ¹	BCG	Intradermal	0.1ml	1D															
Poliomyelitis	IPV	Intramuscular	0.5ml			1D	2D												
	bOPV	Oral	1 capsule or 2 drops					3D								4D			
Diphtheria, tetanus	DTaP	Intramuscular	0.5ml				1D	2D	3D				4D						
	D,T	Intramuscular	0.5ml															5D	
Measles, mumps and rubella	MMR	Subcutaneous	0.5ml									1D		2D					
Japanese encephalitis ²	JE-Live attenuated	Subcutaneous	0.5ml									1D			2D				
	JE-Inactivated	Intramuscular	0.5ml									1D, 2D			3D			4D	
Meningococcal disease	MPSV-A	Subcutaneous	0.5ml								1D		2D						
	MPSV-AC	Subcutaneous	0.5ml													3D		4D	
Hepatitis A ³	HepA-Live attenuated	Subcutaneous	0.5 or 1.0ml											1D					
	HepA-Inactivated	Intramuscular	0.5ml											1D	2D				

Note: 1. Mainly refers to tuberculous meningitis, miliary tuberculosis etc.

2. When the live attenuated JE vaccine is selected, a two-dose vaccination program is used. When inactivated JE vaccine is selected, a four-dose vaccination procedure is used; the interval between the first and second doses of JE inactivated vaccine is 7-10 days.

3. When live attenuated hepatitis A vaccine is selected, a one-dose schedule is used. When inactivated hepatitis A vaccine is selected, a two-dose schedule is used.

NIAC in China advises government authorities on national vaccination strategies and implementation



National Immunization Advisory Committee (NIAC)



- **National Immunization Advisory Committee** plays the same role of NITAG in other countries. It sits in the office of China National Immunization Program office at NHC, which is reporting to the State Council for China's national immunization strategy and plans. It acts as a deliberative body of national experts **who advise national authorities** and policy makers with **evidence-based recommendations on immunization policy and program.**

NIAC Members



- **27 voting members** from across China that have recognised **expertise** in epidemiology, vaccinology, clinical sciences, public health policy, health economics, and immunization
- Each member has a **three-year term** but can only be renewed once
- **One chair and two vice chairs** appointed for three-year terms
- The NIAC follows a **formal member selection and nomination process** to allow the most well recognized and capable experts from across China to serve the panel, and all members will be announced by NHC via a formal document
- The current NIAC members are from **19 different organizations** covering seven fields of expertise

Roles & Responsibilities



- Assess the **evidence of vaccine preventable disease burden**
- **Assess the safety, effectiveness, health economics, and production and supply capacity of new vaccines for recommending introduction into EPI**
- Update recommendations for **vaccines that should be included in the national EPI**
- Provide evidence-based recommendations on immunization program strategies and management

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China EPI is 100% government funded, but the EPI vaccination program is run by each province following the national EPI strategies



Funding & budget



- China EPI is **100% covered by the government budget** (central and provincial funding combined), while the non-EPI vaccines are offered through the public hospitals but paid out of pocket by individuals
- In **2020 and 2021, China EPI spent ~US\$600M and ~US\$540M** respectively on EPI vaccine procurement
- The **EPI budget is expected to increase** when new vaccines incl. Hib, PCV, HPV and Rota are included in the national EPI
- The EPI budget is funded by the **national government** and the Ministry of Finance oversees the budgeting and funding allocation for China EPI

Implementation

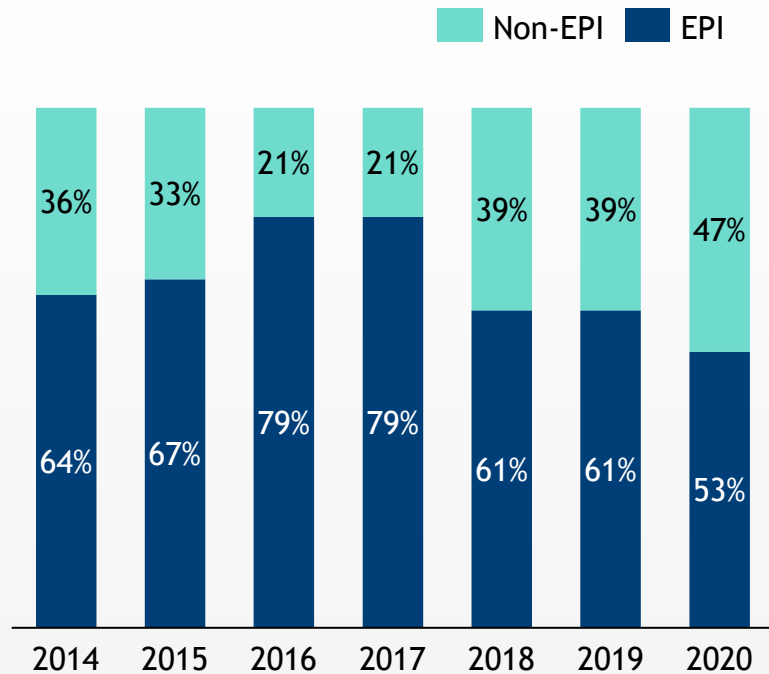


- **National Immunization Advisory Committee (NIAC)** acts as China's National Immunization Technical Advisory Group (NITAG) which advises national authorities and policy makers with evidence-based recommendations on immunization policy and program
- **National Health Commission (NHC)**, with support from China CDC, oversees and coordinates the implementation of the national EPI policy and strategy
- **National Immunization Program under China CDC** provides NAIC and China NHC with technical, program implementation and procurement support for the national EPI implementation at both the national and subnational levels
- Each province is responsible for organizing **vaccination planning and implementation** through its established maternal and child healthcare infrastructure, down to the township and village level health facilities

China vaccines demand has been historically dominated by EPI vaccines, but demand for non-EPI vaccines has increased rapidly since 2017

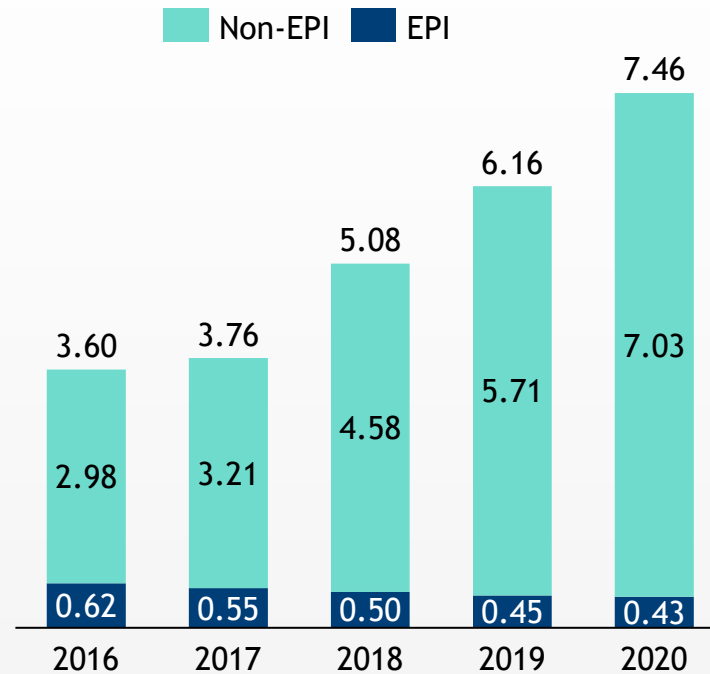


Vax Lot Release Volume by Market Segment (%)



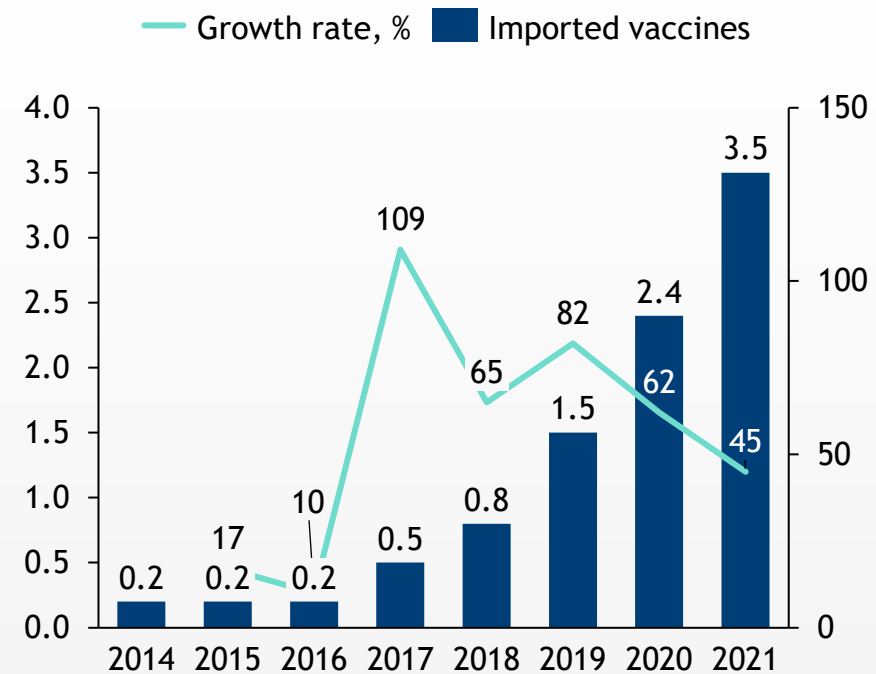
1. Vaccine lot release volume by NMPA does not represent the actual demand or consumption, but it represents total vaccine volumes produced.
2. There is no demand available that shows the annual consumption for non-EPI vaccine consumption.

Sales Revenue by Market Segment (Bn USD)



1. The rapid non-EPI market growth in China is mostly driven by recent years of HPV and PCV13 vaccine intro and scaleup.
2. The household income in China has increased significantly which attributes to increased vaccine awareness, particularly for childhood diseases and cervical cancer prevention.

Market Value of Imported Vaccines (Bn USD)



1. Premier prices for HPV and PCV13, increasing household income as well as vaccine awareness contribute to market sales surge from 2016 to 2019.
2. Global COVID pandemic caused a drop in the market value of imported vaccines, but this is expected to resurge in the next 5 years.

Supply for the 12 EPI vaccines is solely provided by Chinese suppliers

China EPI Vaccine Market Dynamics Overview (Year 2020)

*Fx: 1 USD = 6.7 RMB (July 4, 2022)

EPI Vaccines	Suppliers & Market Share (%)	Price/Course (USD)	Total Market Value (MM USD)
HepB	AIM Hanxin (63%); Kangtai Bio (32%); Huabei Jintai Pharma (5%);	3.22	52.90
BCG	CNBG Chengdu (50%); CNBG Shanghai (50%)	0.73	20.62
IPV	CNBG Beijing (84%); CAMS Kunming Institute (16%);	10.46	163.34
bOPV	CNBG Beijing (90%); CAMS Kunming Institute (10%)	0.81	9.86
DTaP	CNBG Wuhan (71%); CNBG Chengdu (19%); Walvax (10%)	2.12	16.59
DT	CNBG Wuhan (100%)	0.096	2.39
MMR	CNBG Shanghai (68%); CNBG Beijing (32%);	7.41	124.94
JE-L	CNBG Chengdu (62%); CNBG Wuhan (38%)	2.93	34.07
MPSV-A	CNBG Wuhan (100%)	0.39	7.32
MPSV-AC	CNBG Lanzhou (63%); Walvax (37%)	3.56	36.61
Hep A-Live attenuated	Changchun Bio (26%); CAMS Kunming Insititute (43%); Zhejiang Pukang Biotech. (31%)	4.38	58.28
Hep A-Inactivated	Sinovac (81%); Convac (19%);	6.28	6.87

Non-EPI vaccines supply is also dominated by Chinese suppliers

China Non-EPI vaccine Market Dynamics Overview (Year 2021)

Product	Price per course (USD)		Manufacturer	Market Share by China DCVMs	Chinese Suppliers' sales revenue (Bn USD)
PCV13	283.95 - 298.89		Kangtai; Walvax	95%	1.61
PCV23	29.89		Kangtai; Walvax; CNBG Chengdu	95%	0.85
HPV	HPV2	147.50	Innovax; Walvax	100%	0.88
	HPV4	357.77	Merck	95%	0.63
	HPV9	581.94	Merck	95%	5.07
Shingles Vaccine	Recombinant protein	477.93	N.A	0%	0
	Live attenuated vaccine	119.56	Beike Bio, CNBG Shanghai	100%	1.20
Rota	Monovalent/dose	25.70	CNBG Lanzhou; Zhifei	100%	0.03
	5-valent	125.53	Kangtai; CNBG Wuhan (6-valent)	30%	0.19
Hib	59.78		Multiple suppliers	100%	0.18
Rabies vaccine	HDCV	149.45	Kanghua, Kangtai, Zhifei	100%	0.63
	Vero	52.31	Multiple suppliers	100%	0.51
Covid-19	52.31		CNBG Beijing; Sinovac; Cansino, etc	100%	0.75

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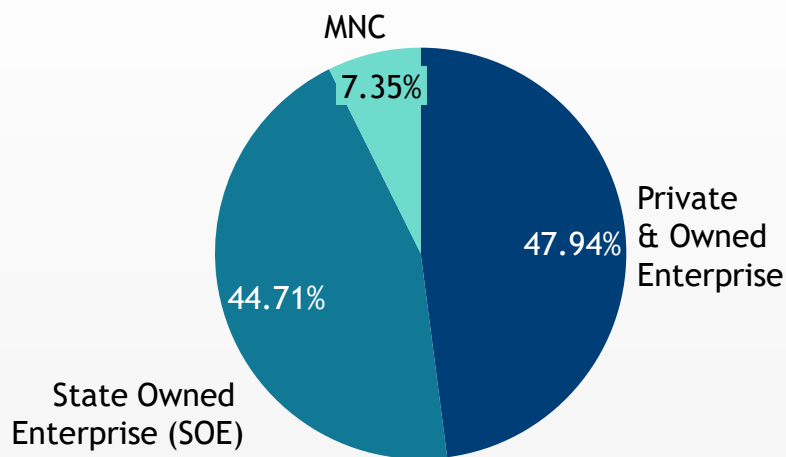
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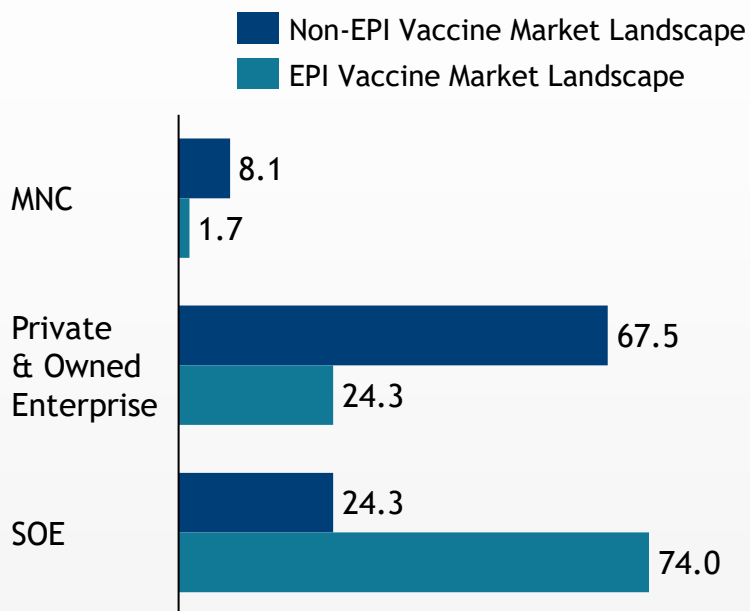
Chinese SOEs are the major supply source of EPI vaccines, but privately owned ones are playing a critical role for non-EPI vaccines supply



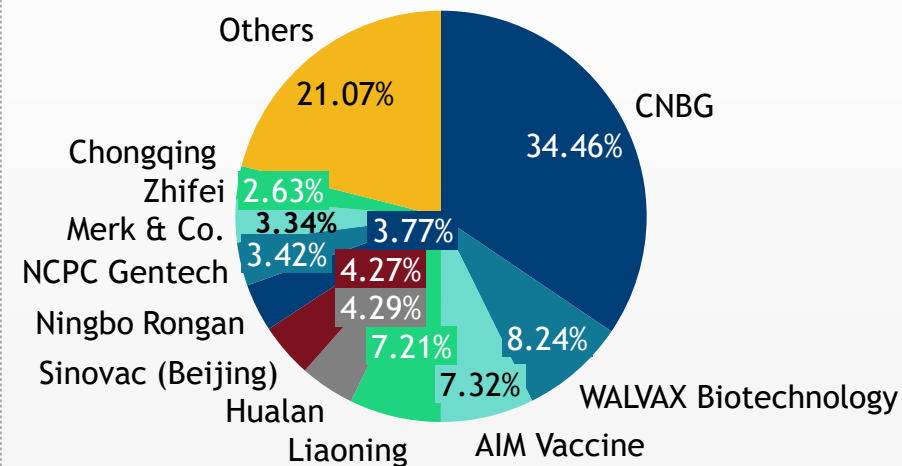
NMPA vaccine lot release volume per supplier type YE2020



China EPI and non-EPI Vaccine market share per supplier-type YE2020



Top 10 vaccine suppliers lot release overview (YE2020)



Key takeaways

1. In 2020, the lot release in China totals ~650M doses, predominantly with ~93% by Chinese companies and ~7% by multinational companies (MNCs).
2. Although MNCs account for a small market share in China, the corresponding market revenue is quite significant due to premier price offerings for novel vaccines incl. IPV, HPV4&9, and PCV13.
3. CNBG is state-owned enterprise and has 70+ years of vaccine production and supply security for China NIP. It has 5 subsidiaries and together they supply 35% of the China NIP.

Since 2014, Chinese vaccine suppliers have started obtaining WHO PQ or EUL status, leading to Gavi/LMIC supply



Vaccines on WHO PQ List (Covid-19 excluded)

Vaccines	Presentation	Schedule	Supplier	Year of WHO PQ obtained	Markets served	China Price/ dose (\$ USD)	UNICEF price/ dose (\$ USD)
JE	5D/Vial	2 doses, 9 mos, 9 mos for 15 yo	CNBG Chengdu	2014	China; Gavi; MIC	EPI	\$0.447
Hep A	1D/Vial	1 dose, 12-23 months of age	Sinovac	2017	China; MIC incl. PAHO	EPI	\$7.55
Flu	1D/Vial	Two-doses, Age 9 and above	Hualan Bio	2015	China; MIC	\$44	N.A.
bOPV	20D/Vial	Four-doses, Birth, 6, 10 and 14 weeks	CNBG Beijing	2019	China; Gavi; MIC	EPI	\$0.12
HPV2	1D/Vial	Two doses, Age 9-14	Innovax	2021	China; Gavi; MIC	\$62	\$2.90
Sabin IPV	1D/Vial	3-doses, months 2 and 3	CNBG Beijing; Sinovac	2022	China; Gavi; MIC	EPI	N.A.
Varicella	1D/Vial	1 dose (booster if required), Age 1 -12	Sinovac	2022	China; MIC incl. PAHO	~\$30	N.A.

Covid-19 vaccines on WHO Emergency Use List

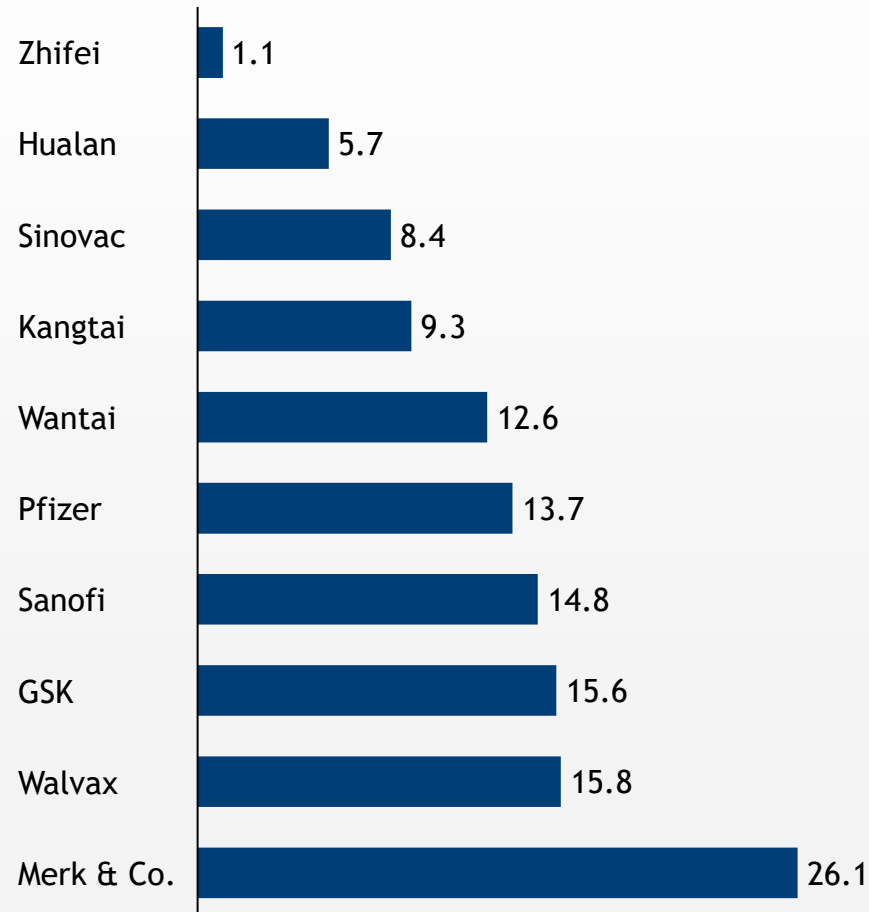
Vaccines	Presentation	Schedule	Supplier	Year WHO EUL	Markets served	Price/ dose (\$ USD)	UNICEF price/ dose (\$ USD)
Covid-19	2D/Vial	2 doses, Age 3 and above	Sinopharm/CNBG	2021	China; COVAX	Gov't funded	N.A.
Covid-19	2D/Vial	2 doses, Age 3 and above	Sinovac	2021	China; COVAX	Gov't funded	N.A.
Covid-19	1D/Vial	1 dose, Age 18 and above	CanSino	2022	China; COVAX	Gov't funded	N.A.

Chinese DCVMs have invested heavily on novel vaccines R&D, aiming to become more competitive in the future China and LMIC markets



R&D Expense/Revenue Ratio (China DCVMs vs MNCs) (2021)

In %



R&D Status of Major Vaccines by Domestic Suppliers (Non-exhaustive)

#	Candidate	Phase	Developer
1	HPV-9	3	Bovax
		3	Innovax
		3	Beijing Health Guard Biotechnology
		3	Jiangsu Ruike
		3	Beijing Abzymo
		3	Walvax Zerun
2	PCV-13	IND	Yidao
		3	CNCG Lanzhou Institute
		3	Zhejiang Vacin Biomedicine
		3	Casino
		BLA	Walvax
		3	Beijing Minhai
		1	Chengdu Antejin
		1	Jiangsu Kunli
3	C-19	3	Walvax
4	MenACYW	3	CNCG Beijing Institute
		3	Kangtai
		3	Beijing Luzhu Biopharm
		3	CNCG Lanzhou Institute
		BLA	Cansino
		3	Kangtai
		1	Suzhouvac
5	Rota	3	CNCG Lanzhou Institute
		3	CNCG Wuhan Institute
		1	Zhifei
		1	CAMS Kunming Institute

Non-Chinese DCVMs and MNCs may also be interested in China vaccine market supply in the future



Chinese Suppliers

- Approximately **700 million vaccine doses** are produced annually in China, making China one of the world's largest vaccine producer.
- China has 40+ NMPA approved Vx suppliers.
- China NMPA is a functional ML3 NRA, and 6 Chinese vaccines have passed WHO PQ since 2014.



Multinational Companies (MNCs)

- Sanofi Pasteur, Novartis, Merck, Pfizer and GSK are among those that have been supplying to both China EPI and non-EPI programs.
- Pfizer's PCV-7 and PCV-13 have continuously taken up the non-EPI market share in China, while Merck's HPV-4 and HPV-9 are increasingly popular in China.



Non-Chinese DCVMs

- Since 2016, China has further loosened up its regulatory requirement for generic vaccines and drugs to be registered and marketed in China, but we have not seen any non-Chinese companies breakthrough in the China market.

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China's vaccine development and registration process is similar to the US and Europe, with additional dossier translation



Clinical Development

- Vx developers, domestic or international, need to file NDA with China NMPA, and once filed, clinical trials (Phase 1-3) shall be conducted in China strictly in line with NMPA regulations
- Vx clinical development and approval follows the same process as new drugs



Registration

- In case of public health emergency, Vx developers can pursue emergency use authorization for fast-track approval to use in China, but still need to obtain formal approval once clinical data are validated and approved.
- Priorities will also be given for vaccines that contribute to epidemic preparedness and disease control.



Production & Lot Release

- Only cGMP compliant Vx producers are approved for Vx production, sales and distribution in China
- All cGMP certified producers must receive routine and fly-in inspections by national and provincial Medical Products Administration agencies to ensure quality assurance.
- Vx producers need to apply for lot release approval for each single lot that is planned for production, and the same process applies to MNCs and DCVMs.



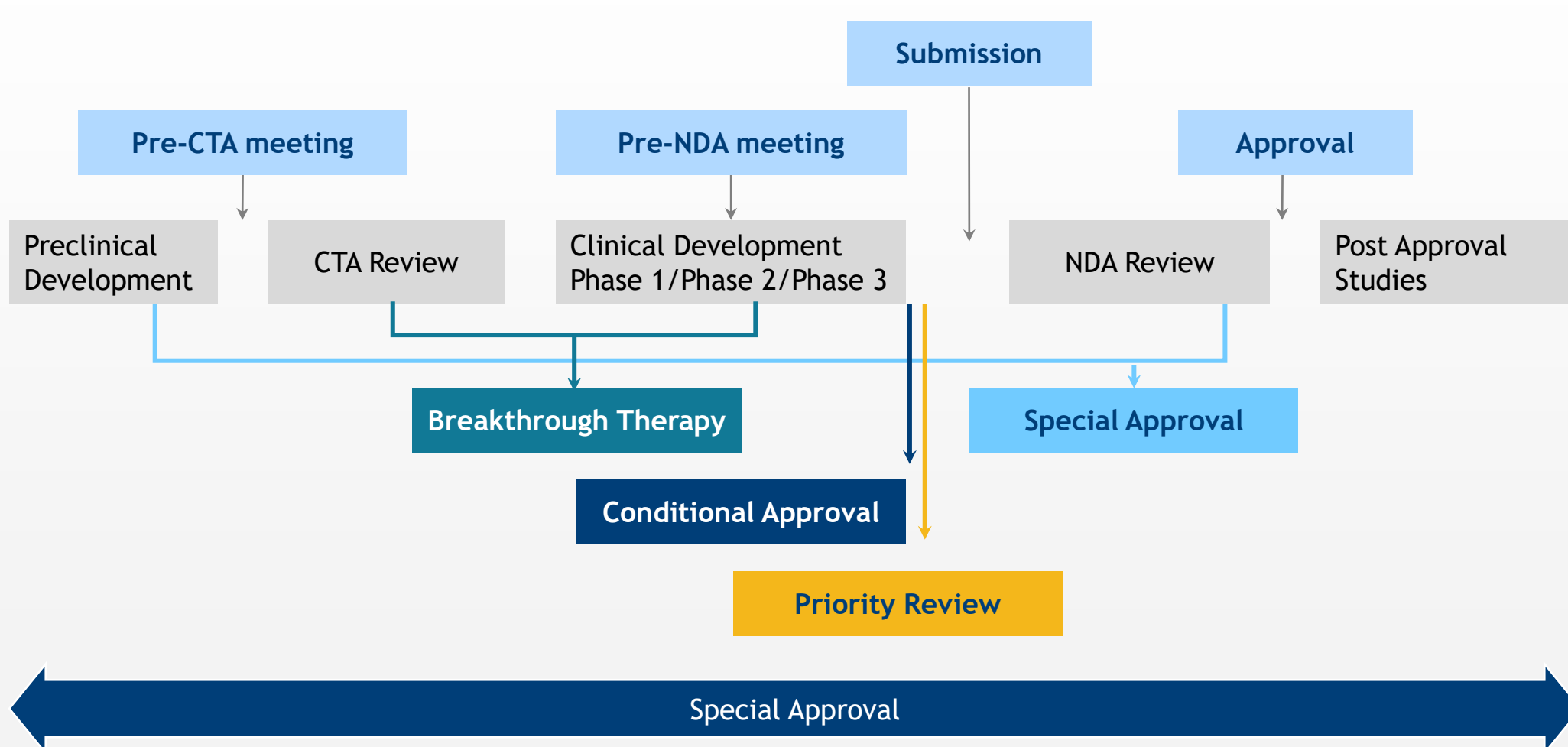
Procurement

- China adopts the centralized Vx procurement process at the national level for all EPI vaccines, and they are jointly organized by NHC, NHSA and Ministry of Finance. Prices negotiated at the national level are applicable to all provinces for contracting and delivery. All EPI vaccines are 100% funded by the national budget.
- Non-EPI Vx are procured at each provincial level through government-led public goods trading platforms.

Vaccine products follow the same clinical development, approval, and registration process that is enforced by China NMPA



New Drug Development and Approval Process in China



Upon completing the in-country clinical trials, the review and approval process can be as long as 6-7 months



Regulatory Body:	<i>National Medical Products Administration (NMPA)</i>
Expected Cost:	<ul style="list-style-type: none"> - <i>Vx produced inside China: ~US\$9,400</i> - <i>Vx produced outside China: ~US\$11,000</i>
Expected time for registration:	<i>200 working days</i>
Fast-track approval time:	<i>As short as 20 - 25 days in the case of public health crisis (e.g Covid 19)</i>

Requirements	Notes
Application approval	An approval of a vaccine registration application requires the approval of production process, quality control standards, instructions and labels of vaccines.
Local Safety/ Efficacy data	Local Phase III clinical trials are required to comprehensively evaluate the protective effect and safety of the vaccine, and this phase is the basis for obtaining registration approval.
GMP inspection	Vaccines shall be produced and inspected in accordance with the approved production process and quality control standards, and the entire production process shall comply with the requirements of the Good Manufacturing Practice for Drugs.
Product samples	If there is any doubt about the authenticity of the vaccine batch release application materials or samples, the batch issuing agency shall verify it, and if necessary, shall organize on-site verification by means of on-site sampling inspection.
Local country registration or an in-country distributor	Local vaccines shall apply for a certificate of batch issuance; imported vaccines shall also provide a certificate of origin and a certificate of batch issuance.



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