

3 December 2020

Covid-19 vaccine update

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The Covid-19 vaccination race has just begun; India aptly placed

Global cases of Covid-19 continue rising; a vaccine is an essential measure to counter the next wave. Recent data for three vaccines have raised expectations; an approved one is likely in the next few weeks. Pfizer and Moderna have filed applications with the US FDA under emergency-use authorisation; decisions regarding them could be taken in the next few days. While most countries are trying to obtain dosages for their people, India has secured over 1.6bn doses through vaccine manufacturers. Seven Indian pharma companies have collaborated or are working on an indigenous vaccine. We expect AstraZeneca-Serum to be the first to be commercially available in India. The government plans to vaccinate 200m-250m citizens by Jul'21.

Number of vaccine candidates on the rise. Globally, 237 Covid-19 vaccine candidates are now in trials, 13 of them in late phase-2/-3. Overall, there are 8-9 mechanisms through which scientists the world over are trying to develop a vaccine. Pfizer and Moderna have RNA-based vaccines, while over 77 vaccines (mostly in early stages) are being developed using the protein-subunit platform. With regulators setting a benchmark 50% efficacy level, we will see some more candidates clearing the regulations in the next few months.

Countries line up to secure doses. Of developed economies, Canada, the US, the EU, Australia and Japan have already secured sufficient doses (over 100% of their population) to vaccinate all. Nearly 54% of committed doses have been secured by high-income countries, while the share of low- and middle-income countries was 36%; 10% is by institutions such as Covax.

India well placed among emerging markets. India has secured 1.6bn doses for its population. It has entered into agreements with AstraZeneca for 500m doses, Novavax (1bn doses) and Gamaleya (100m).

Government may lever existing UIP platform. India conducts one of the largest Universal Immunisation Programmes (UIP) in the world, through which it administers 390m doses annually at 9m sessions across the country to 26m children and 30m pregnant women. The government may use this readily available platform to conduct a Covid-immunization programme.

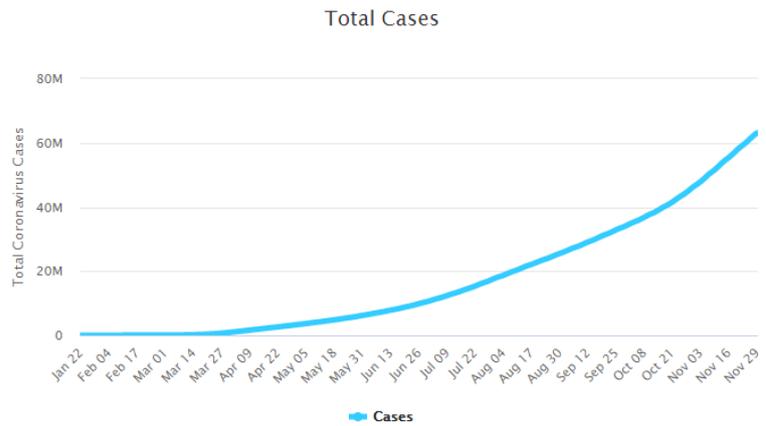
India to become a Covid-19 vaccine manufacturing hub. India has the ability to manufacture over 3bn doses annually. Eight Indian manufacturers have signed up with foreign collaborators or are developing a vaccine indigenously. At present, AstraZeneca and The Serum Institute of India are likely to launch their vaccines in Feb'21 followed by Zydus Cadila, Dr Reddy's/Hetero and Bharat Biotech. Others in the race are Biological E, Indian Immunologicals and Mynvax.

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Globally, 63m cases of Covid-19 have been registered. The US, India, Brazil, Russia and the EU have been hardest hit

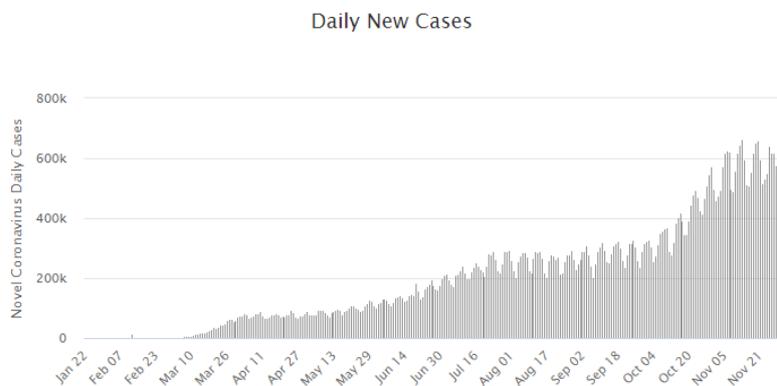
Fig 1 – Number of Covid-19 cases continue rising



Source: Worldometer

The US accounts for 28% of new cases daily, followed by India, Turkey, Russia and Brazil

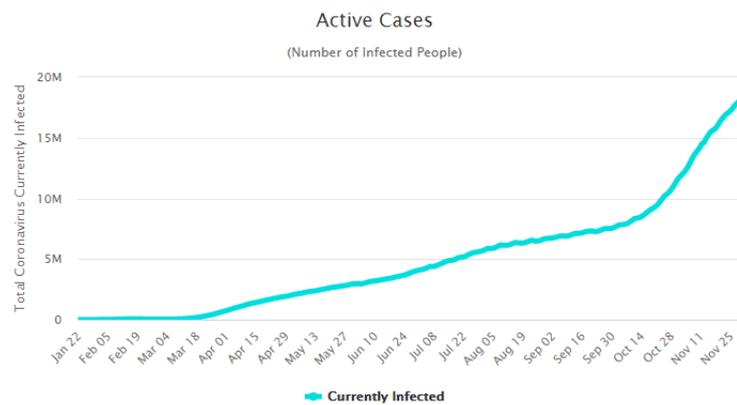
Fig 2 – Number of infections have soared to over 500,000 a day



Source: Worldometer

The 70% recovery rate is helping keep the number of active infections low

Fig 3 – Over 18m active infections around the globe



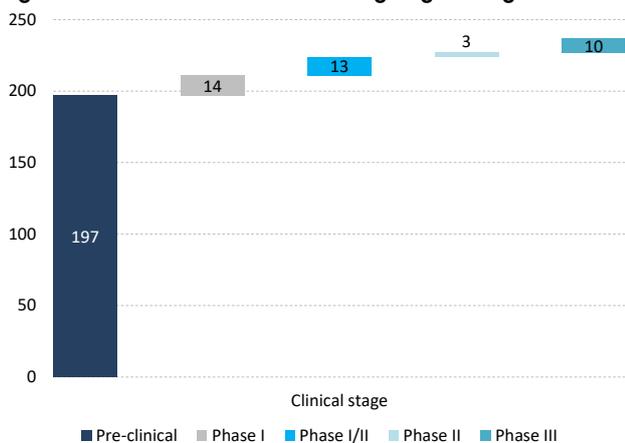
Source: Worldometer

Fight against Covid-19 getting intense

Across the globe pharma and biotech companies have increased spending on developing a vaccine or drug to fight Covid-19. At present ~237 vaccines and 319 drugs are being developed or for which clinical trials are ongoing.

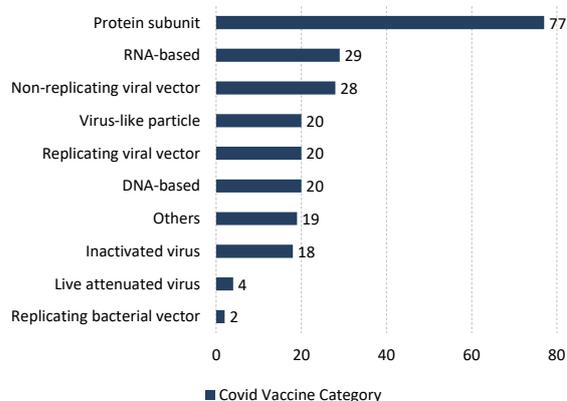
Companies have been trying to develop a vaccine on 8-10 platforms. Initially most vaccine manufacturers preferred RNA- and DNA-based platforms. However, with initial successes in Ebola and Hep-B vaccines the focus has now shifted to a protein-subunit platform with over 77 candidates being at the pre-clinical stage.

Fig 4 – 10 vaccine candidates undergoing last leg of trials



Source: Milken Institute, Anand Rathi Research

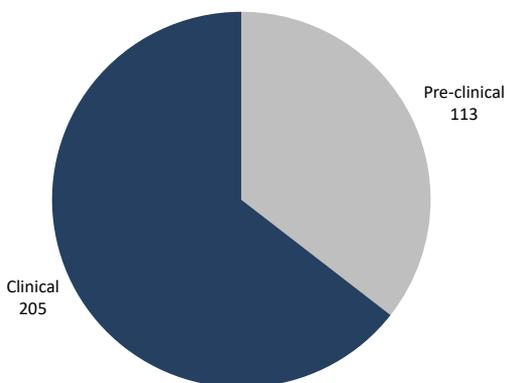
Fig 5 – Protein subunit emerging as a vaccine-development platform



Source: Milken Institute, Anand Rathi Research

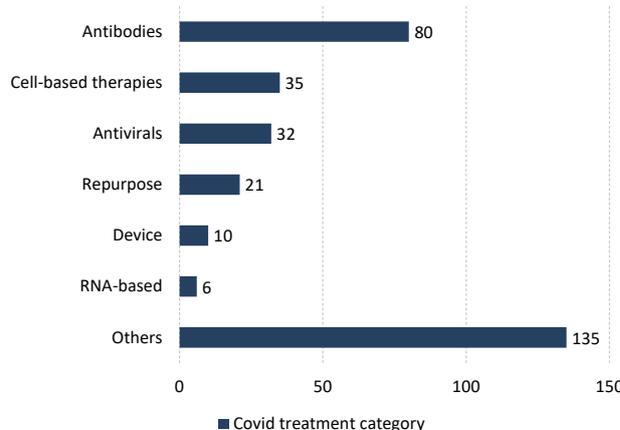
At present, remdesivir has been prescribed for critical Covid-19 patients and favipiravir for mild/moderate patients. With recent data from trials suggesting very limited benefits from these drugs, the urgent need is for an effective drug to be developed and launched to control the spread of Covid-19. At present 205 drugs are at various stages of trials while 113 are at the initial stage.

Fig 6 – Robust pipeline for Covid-19 treatment



Source: Milken Institute, Anand Rathi Research

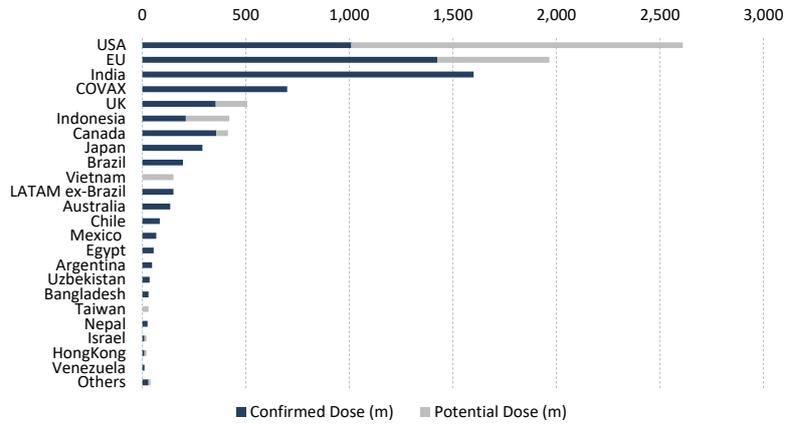
Fig 7 – Antibodies/cell-based therapies gaining momentum



Source: Milken Institute, Anand Rathi Research

Most countries securing doses

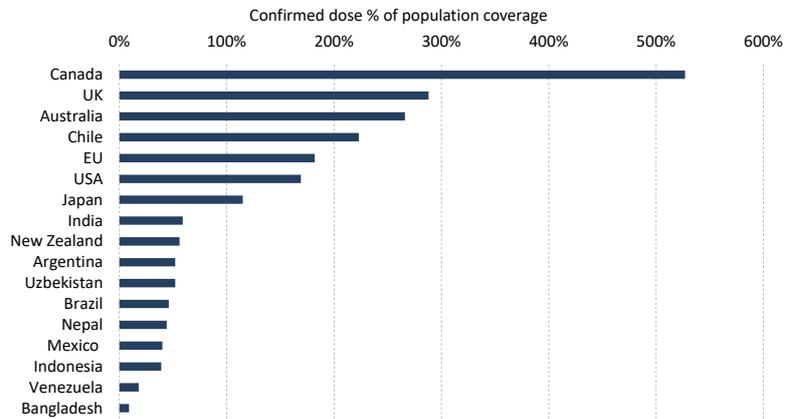
Fig 8 – The US, the EU and India have secured the most doses



65% of currently available doses of vaccines have already been secured by a few nations

Source: Duke University, Anand Rathi Research

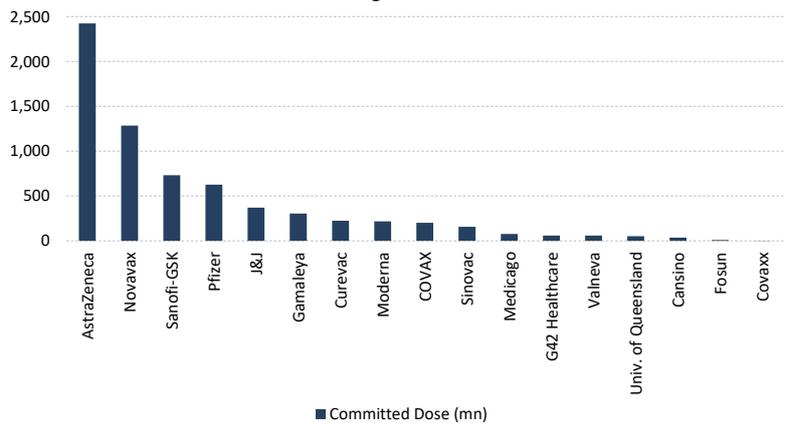
Fig 9 – Most high-income nations have secured doses far exceeding populations



Canada has secured doses of nearly 5x its population. The UK and Australia have secured doses of more than 2x their populations

Source: Duke University, Anand Rathi Research

Fig 10 – Vaccine manufacturers have agreements for over 6.8bn doses

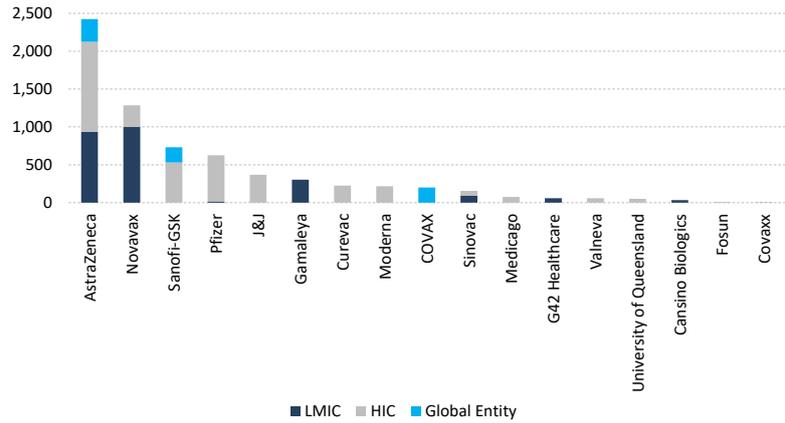


AstraZeneca has already committed over 2.5bn doses, followed by Novavax, Sanofi-GSK and Pfizer

Source: Industry, Anand Rathi Research

Rich nations have cornered 54% of available doses while the share of low- and mid-income countries is 36%. ~10% of doses have been secured by donor-funding institutions such as Covax

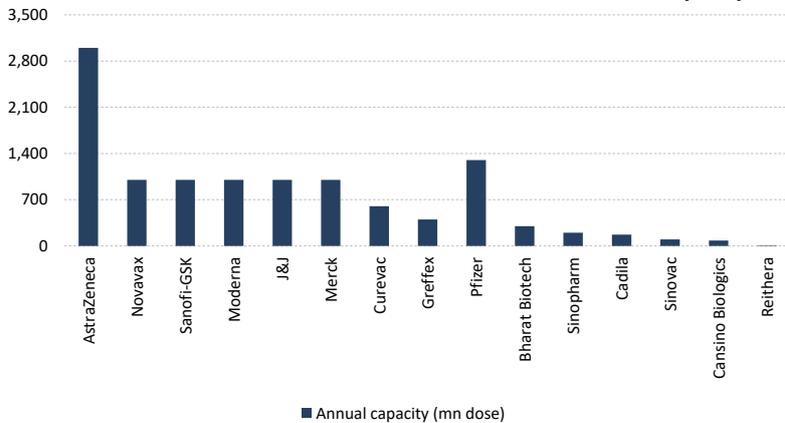
Fig 11 – Nearly 54% of doses committed to high-income nations; LMIC at 36%



Source: Industry, Anand Rathi Research

AstraZeneca and The Serum Institute of India are likely to have capacity to manufacture 3bn doses annually

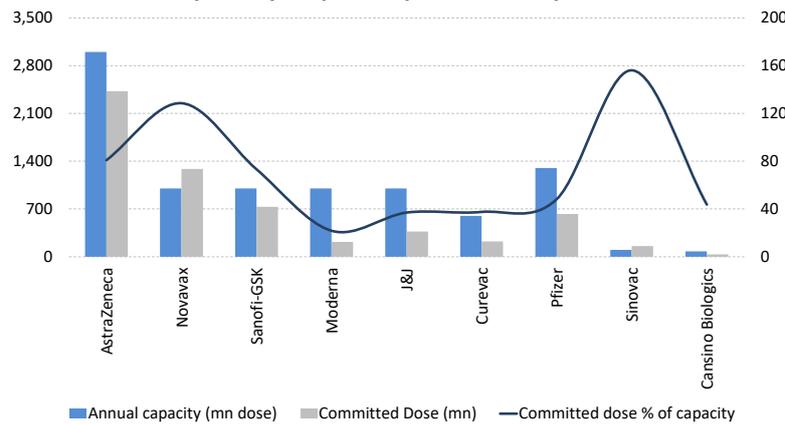
Fig 12 – Of all manufacturers, AstraZeneca has the most available capacity



Source: Industry, Anand Rathi Research

AstraZeneca, J&J, Sanofi-GSK and Novavax have commitments almost similar to their annual capacities

Fig 13 – ~63% of first-year capacity already committed by vaccine manufacturers



Source: Industry, Anand Rathi Research

Vaccine manufacturers leading the race

Pfizer and BioNTech

Pfizer and BioNTech have reported 95% efficacy in each case measured seven days after the second dose, post-phase3 studies on their mRNA-based Covid-19 vaccine candidate, BNT162b2. Phase-3 clinical trials of BNT162b2 began on 27th Jul'20, with 43,661 participants, 41,135 of whom have received a second dose of the vaccine candidate as of 13th Nov'20. ~42% of global participants and 30% of U.S. participants have racially and ethnically diverse backgrounds; 41% of global and 45% of U.S. participants are 56-85 years old.

Pfizer has conducted clinical trials at 150 sites in the US, Germany, Turkey, South Africa, Brazil and Argentina. To collect efficacy and safety data, trials will continue for a further two years. Pfizer and BioNTech have submitted requests to the US FDA for emergency-use authorisation (EUA) of their Covid-19 vaccine candidate. It expects EUA approval from the FDA by 10th Dec.

Moderna

Moderna's phase-3 vaccine candidate, mRNA-1273, has met statistical criteria pre-specified in the study protocol for efficacy, with a vaccine efficacy of 94.5%. The company conducted a phase-3 trial with over 30,000 participants in the U.S. The primary endpoint of the phase-3 COVE study was based on analyses of Covid-19 cases confirmed and adjudicated, starting two weeks after the second dose of the vaccine.

The interim analysis was based on 95 cases, of which 90 Covid-19 cases were observed in the placebo group vs. five in the mRNA-1273 group, resulting in an estimated 94.5% efficacy. Based on these interim safety and efficacy data, Moderna has applied to the US FDA for EUA for its vaccine. It expects EUA approval from the FDA by 17th Dec. It plans to submit marketing authorisation applications to global regulatory agencies.

Astra Zeneca, Oxford

An interim analysis of clinical trials of AZD1222 in the UK and Brazil showed the vaccine was highly effective in preventing Covid-19. One dosing regimen given to 2,741 participants showed a 90% efficacy with a half dose of AZD1222 followed by a full dose at least a month apart. Another dosing regimen to 8,895 participants showed 62% efficacy with two full doses at least a month apart. The combined analysis from both dosing regimens resulted in an average efficacy of 70%.

Over 23,000 participants are being assessed following two doses of either a half-dose/full-dose regimen or a two-full-dose regimen of AZD1222 or a comparator or saline. In the interim analysis there were 131 Covid-19 cases. The company has initiated another trial in the US with a lower dose. It plans to file for regulatory approval in the UK and the EU. In India AstraZeneca has a tie-up with The Serum Institute of India, which is likely to file for approval with the Indian regulator in the next few weeks.

Fig 14 – Key vaccine candidates in clinical trials

Candidate	Mechanism	Sponsor	Clinical phase	No. of doses required	Dose interval	Route of administration	Temperature	Annual capacity (m doses)
AZD1222	Replication-deficient viral vector vaccine (adenovirus from chimpanzees)	The University of Oxford; AstraZeneca; IQVIA; The Serum Institute of India	Phase-3	2	0, 28 days	Intramuscular	2° to 8° C	3,000
BNT162	mRNA-based vaccine	Pfizer, BioNTech	Phase-3 / filed with the FDA under the EUA	2	0, 28 days	Intramuscular	-60° to -90° C	1,300
mRNA-1273	mRNA-based vaccine	Moderna	Phase-3 / filed with the FDA under the EUA	2	0, 28 days	Intramuscular	-20° C for six months, 2° to 8° C for 30 days	1,000
Ad5-nCoV	Recombinant vaccine (adenovirus type 5 vector)	CanSino Biologics	Phase-3	1	-	Intramuscular	-	70-80
CoronaVac	Inactivated vaccine (formalin with alum adjuvant)	Sinovac	Phase-3	2	0, 14 days	Intramuscular	-	100
Covaxin	Inactivated vaccine	Bharat Biotech; The National Institute of Virology	Phase-3	2	0, 28 days	Intramuscular	-	300
JNJ-78436735 (formerly Ad26.COV2.S)	Non-replicating viral vector	Johnson & Johnson	Phase-3	1/2	0 / 0, 56 days	Intramuscular	2° to 8° C	1,000
No name announced	Inactivated vaccine	Wuhan Institute of Biological Products; China National Pharmaceutical Group (Sinopharm)	Phase-3	2	0, 21 days	Intramuscular	-	NA
NVX-CoV2373	Nanoparticle vaccine	Novavax	Phase-3	2	0, 21 days	Intramuscular	2° to 8° C	1,000
Sputnik V	Non-replicating viral vector	Gamaleya Research Institute, Acellena Contract Drug Research and Development	Phase-3	2	0, 21 days	Intramuscular	-20° C in liquid form, 2° to 8° C in lyophilised	NA
INO-4800	DNA vaccine (plasmid)	Inovio Pharmaceuticals	Phase-2 / -3	2	0, 28 days	Intradermal	-	NA
VIR-7831	Plant-based adjuvant vaccine	Medicago; GSK; Dynavax	Phase-2 / -3	2	0, 21 days	Intramuscular	-	NA
ZyCoV-D	DNA vaccine (plasmid)	Zydus Cadila	Phase-2	3	0, 28, 56 days	Intradermal	-	150-170
No name announced	Protein-subunit vaccine	Sanofi; GlaxoSmithKline	Phase-1 / -2	2	0, 21 days	Intramuscular	2° to 8° C	1,000
CVnCoV	mRNA-based vaccine	CureVac	Phase-1	2	0, 28 days	Intramuscular	2° to 8° C	600-1,000
V590	Recombinant vaccine (vesicular stomatitis virus)	Merck; IAVI	Phase-1	1	-	Intramuscular	-	1,000

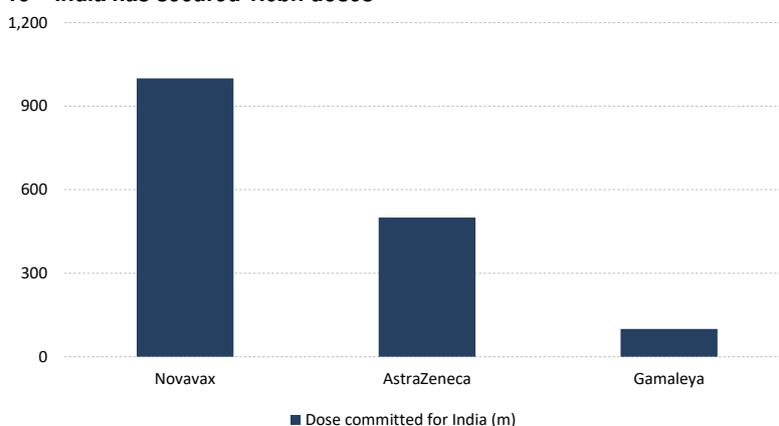
Source: Industry, Anand Rathi Research

India aptly placed to gain from Covid-19 vaccine supplies

The Indian government has been proactive in securing vaccine doses. At present it has commitments for more than 1.6bn doses from three manufacturers who have a vaccine in phase-3 trials. The number of committed doses can be injected into ~800m people, enough to cover the vulnerable population.

Over 60m doses will be initially provided to healthcare professionals, frontline workers and police & armed force personnel. Then, over 600m doses will be provided to citizens with co-morbidities and those over 50 years.

Fig 15 – India has secured 1.6bn doses



Source: Duke University, Anand Rathi Research

India is one of the leading vaccine manufacturers globally and key vaccine manufacturers have sped up efforts to collaborate with global partners or develop a vaccine indigenously. The global Covid-19 vaccine market is expected to cross \$150bn-160bn (assuming a blended cost of \$10 a dose and two doses required per person). India can play a pivotal role considering it hosts one of the largest vaccine manufacturing sites in the world; others too are ramping up capacities.

Fig 16 – Indian vaccine manufacturers are increasing efforts to gain access to a vaccine

Indian player	Partner	Mechanism	Clinical trial	Expected Approval	Capacity (doses)	No. of doses	Temperature
Serum	AstraZeneca	Replication-deficient viral vector	Phase-3	Dec'20	500m	2	2° to 8° C
Zydus Cadila	Indigenous	DNA	Phase-3	Mar'21	170m	3	-
Dr Reddy's / Hetero	Russian Direct Investment Fund (Gamaleya)	Non-replicating viral vector	Phase-3	Mar'21	100m	2	-20°C in liquid form, 2° to 8° C in lyophilised
Bharat Biotech	Indigenous	Inactivated vaccine	Phase-3	Mar'21	300m	2	-
Serum	Novavax	Nanoparticle vaccine	Phase-3	Jun'21	1bn	2	2° to 8° C
Biological E	J&J	Non-replicating viral vector	Phase-3	Jun'21	-	1/2	2° to 8° C
Aurobindo	-	-	-	-	450m	-	-
Bharat Biotech	Washington University School of Medicine	Adenovirus	Phase-1	2021-22	-	-	-
Serum	Codagenix	Live-attenuated	Pre-clinical	2021-22	-	-	-
Indian Immunologicals	Griffith University	Live-attenuated	Pre-clinical	2021-22	-	-	-
Mynvax	-	-	Pre-clinical	2021-22	-	-	-
Biological E	Baylor College of Medicine	Adjuvanted protein subunit	Phase-1/-2	2021-22	-	-	-

Source: Industry Anand Rathi Research.

The Serum Institute of India

Established in 1966, The Serum Institute of India Pvt. Ltd. is the world's largest manufacturer of vaccines (by volumes). It sells over 1.5bn doses globally and is one of the cheapest and WHO-accredited vaccine supplier to 170 countries.

The SII has entered into an agreement with AstraZeneca in India to develop and manufacture in India the latter's Covid-19 vaccine. The vaccine will be named Covishield in India. The SII together with the ICMR is conducting phase-2/-3 clinical trials at 15 centres in India. On 31st Oct'20 it completed enrolling 1,600 participants. Covishield is likely to be the first vaccine to be commercialised in India, first sold to the government at Rs225 a dose, then in the open market at Rs500-600 a dose.

The ICMR and the SII have further collaborated in the clinical development of Covovax, developed by Novavax and to be manufactured in India by the SII. The agreement with Novavax permits the SII to manufacture 1bn doses.

Zyventus Cadila

Cadila is developing indigenously a plasmid DNA Covid-19 vaccine candidate (ZyCoV-D) at its Vaccine Technology Centre in Ahmedabad, India. Phase-2 trials have been completed and the company is likely to apply for permission to begin phase-3 with over 39,000 participants. Phase-3 clinical trials are expected to begin in Dec'20; if successful, the vaccine might be launched by Mar'21. The company has capacity to manufacture 100m doses and may add 50m-70m dose capacity through third-party manufacturers.

Dr Reddy's

Dr Reddy's has entered into an agreement with Russia's sovereign wealth fund, The Russian Direct Investment Fund (RDIF), to source the Sputnik-V vaccine developed by The Gamaleya National Research Institute of Epidemiology and Microbiology. The agreement permits Dr Reddy's to conduct clinical trials and distribute in India ~100m doses of the Sputnik-V vaccine. This vaccine has been developed on an adenoviral-vector platform and is in phase-3 trials in India. RDIF has further collaborated with Hetero Drugs to manufacture 100m doses of the Sputnik-V vaccine.

Aurobindo

Aurobindo is building a new vaccine plant, expected to be ready by Apr'21, likely to have capacity to manufacture 450m doses of vaccines. It will be capable of manufacturing vaccines on most virus-vector platforms, incl. mRNA and DNA technologies. It is seeking to collaborate with partners who are looking to scale up their vaccine candidates. Besides, it has partnered with three CSIR labs—The Centre for Cellular and Molecular Biology (CCMB), Hyderabad; The Institute of Medical Technology (IMTECH), Chandigarh; and The Indian Institute of Chemical Biology (IICB), Kolkata—for three vaccines now at clinical stages.

Bharat Biotech

Bharat Biotech is developing indigenously a Covid-19 vaccine, Covaxin, in collaboration with The ICMR and The National Institute of Virology (NIV). The indigenous, inactivated vaccine will be developed and manufactured at its Bio-Safety Level-3 (BSL-3) high-containment plant. Phase-1 and -2 trials have been completed; after interim analysis Covaxin

has received DCGI approval for phase-3 clinical trials. The company will conduct phase-3 trials with ~26,000 participants in over 25 centres across India.

Biological E

Biological E has entered into an agreement with Janssen Pharmaceuticals (J&J) to manufacture drug substances and drug products for J&J's Covid-19 vaccine candidate, Ad26.COVS, now in phase-1 and -2a clinical trials.

Also, it has in-licensed a protein subunit Covid-19 vaccine from BCM Ventures and The Baylor College of Medicine. It has initiated phase-1 and -2 clinical trials in India following approval from The Drug Controller-General of India (DCGI). Results are expected by Feb'21.

Indian Immunologicals

Indian Immunologicals has collaborated with The Griffith University of Australia to conduct exploratory research to develop a lead vaccine candidate for Covid-19. It will develop a live attenuated vaccine using the latest codon de-optimisation technology. On completion of the research, the vaccine strain will be transferred to Indian Immunologicals, which will conduct clinical trials in India.

India’s edge in vaccine administration

India conducts one of the largest universal immunisation programs (UIP) globally. Annually, it immunises ~26m infants and ~30m pregnant women. The vast scale of India’s UIP is supported by more than 27,000 functional cold-chain points including ~76,000 cold-chain equipment, ~2.5m health workers and ~55,000 cold-chain staff (cold-chain technicians and vaccine and cold-chain handlers). Through UIP the government administers around 390m doses annually at 9m sessions across India.

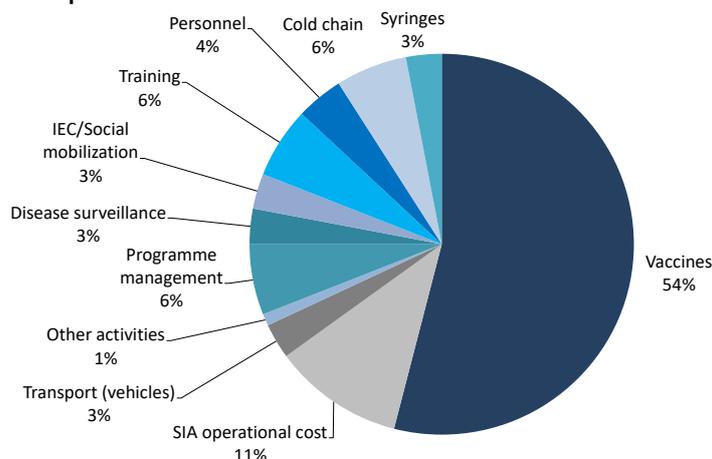
Fig 17 – India’s public medical cold-chain infrastructure

Equipment	Numbers in 2017 (existing + new)	Price per unit (Rs)
Walk-in coolers	247	16,84,620
Walk-in freezers	51	14,07,635
Ice-lined refrigerators	35,776	87,900
Deep-freezers	31,987	78,400
Solar direct-drive refrigerators	100	4,55,000
Cold boxes	79,358	5,000
Hybrid cold-chain systems	407	16,00,000
Vaccine carriers	14,43,945	431
Ice packs	11,81,594	14
Voltage regulators	24,415	2,267
Toolkits for technicians	175	1,32,000
Vaccine vans	700	8,00,000
Teeka Express	120	6,00,000

Source: The Ministry of Health and Family Affairs, GoI; Anand Rathi Research

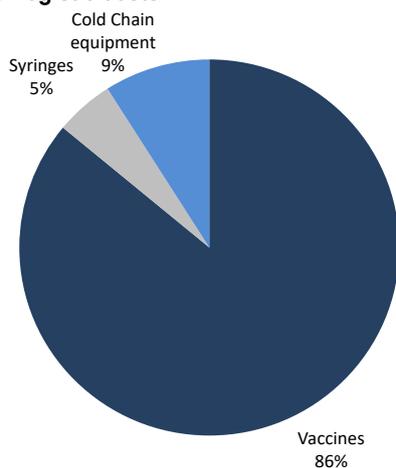
At present, the average cost of a vaccine dose under the UIP is less than \$1 and the vaccine cost makes up only 54% of the immunisation cost (excl. shared employee costs). Data available show that the AstraZeneca-Serum vaccine is likely to cost the government Rs225 a dose (Rs500-600 in the open market). The cost of immunization of 200m-250m people implies an expected outlay of over \$1.5bn.

Fig 18 – Components of immunisation cost under the UIP



Source: The Ministry of Health and Family Affairs, GoI; Anand Rathi Research

Fig 19 – Distribution of logistic costs



Source: The Ministry of Health and Family Affairs, Gol; Anand Rathi Research

Fig 20 – In the overall chain, the cost of syringes is low

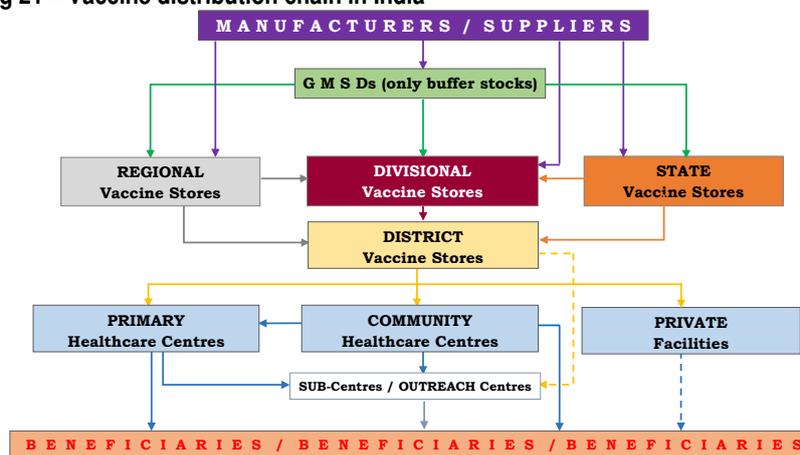
Syringes	Price per unit (Rs)
0.5 ml	1.9
5 ml	1.6
0.1 ml	1.8

Source: The Ministry of Health and Family Affairs, Gol; Anand Rathi Research

Medical cold-storage setup in India

The vaccine cold-chain network in India comprises four government medical-store depots (GMSDs), 39 state vaccine stores, 123 divisional vaccine stores, 644 district stores and 22,674 Community Health Centre/Primary Health Centre (CHS/PHC) stores.

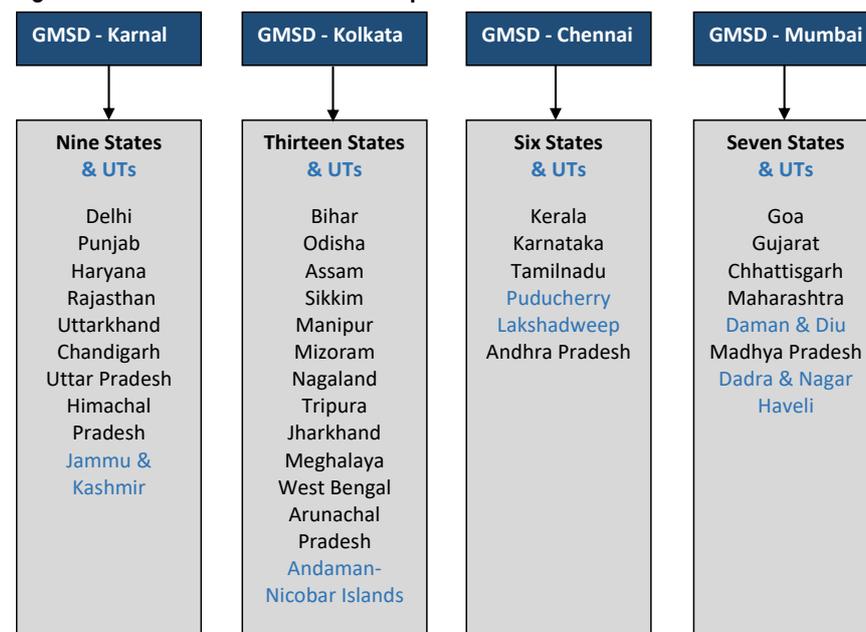
Fig 21 – Vaccine distribution chain in India



Source: The Ministry of Health and Family Affairs, GoI; Anand Rathi Research

The required vaccine arrives directly at state and division stores. ~20% of the annual requirement is supplied to GMSDs (four, at Karnal, Chennai, Mumbai and Kolkata) where stock is maintained for three months maximum. These depots supply the state and Union Territories. Usually, 80% of the vaccines are supplied directly to state and/or divisional/regional vaccine stores by manufacturers/suppliers.

Fig 22 – Government medical-store depots network in India



Source: The Ministry of Health and Family Affairs, GoI; Anand Rathi Research

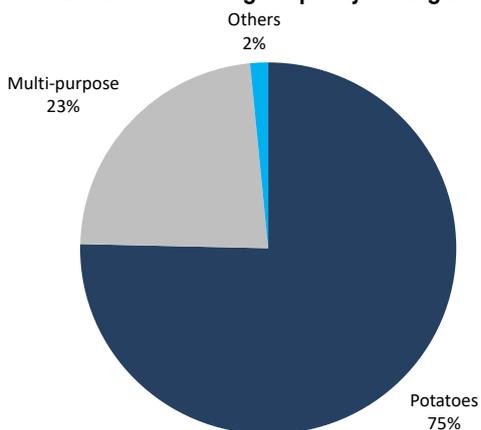
Fig 23 – Temperature sensitivity of vaccines supplied currently under the UIP

WHO Norm	Vaccine	Primary	Intermediate			Health Centres (CHC/PHC/UHC)
		GMSD	State	Division	District	
UIP Vaccines	OPV	-15 ^o to -25 ^o C				+2 ^o to +8 ^o C
	BCG	+2 ^o to +8 ^o C				
	JE					
	HepB					
	DPT					
	DPT-Hib-HBV (pentavalent liquid)					
	TT					
	Measles					
Additional Vaccines	MMR	+2 ^o to +8 ^o C				
	MR					
	IPV					
	PCV					
	Rotateg (RV-5)					
	Rotarix (RV-1)	-15 ^o to -25 ^o C				
	ROTAVAC (116E)					

Source: The Ministry of Health and Family Affairs, GoI; Anand Rathi Research

At present, ~60% of cold-storage capacity is concentrated in Uttar Pradesh and West Bengal. 77% are single-commodity cold storages (mainly for potatoes); 23% are multi-commodity.

Fig 24 – A mere 23% of India’s cold storage capacity is fungible



Source: 2010 Global Capacity Report by The International Association of Refrigerated Warehouses

Annexure

Annexure 1 – Private vaccine manufacturers in India

Sr. No.	Manufacturer	Licensed vaccines
1	Bharat Biotech International	Hib, Rabies, bOPV, mOPV, DTP+Hib+Hep B, Vi polysaccharide Typhoid, H1N1, DTP, DTP+HepB, Rotavirus vaccine, inactivated JE vaccine, Typhoid+TT Conjugate vaccine and DTP+Hib
2	Biological E	DTP, DT, Diphtheria, Pertussis, DTP+Hep-B, Hib, JE, Tetanus Toxoid, Hep-B, DTP+HepB+Hib, DT & IPV
3	Biomed Pvt. Ltd.	Hib, Meningococcal Polysaccharide (A,C, Y,W 135), bOPV, Vi Polysaccharide Typhoid Vaccine and Meningococcal polysaccharide (A & C), rabies
4	Cadila Healthcare	Pandemic influenza H1N1 2009 monovalent vaccine, Typhoid vaccine, Rabies vaccine, Tetravalent Influenza
5	Cadila Pharmaceuticals	H1N1 VLPs vaccine
6	Chiron Behring	Rabies vaccine
7	Dano Vaccine and Biological Pvt. Ltd.	Tetanus Toxoid
8	Green Signal BioPharma	BCG vaccine
9	Panacea Biotech	DTP, HepB, DTP+Hep-B, DPT+Hep-B+Hib, IPV, Hib and H1N1, bOPV, DTP-Hib, DPT+HepB+Hib+IPV
10	Sun Pharma (Ranbaxy)	Typhoid polysaccharide and Hib Conjugate vaccine
11	The Serum Institute of India	DTP, DT, Hep-B, Hib, MMR, Measles, Rubella, BCG, Rabies, IPV, DTP+ Hep B+ Hib, DTP+HepB, DTP+Hib, H1N1, Meningococcal A conjugate, Mumps, MR, H1N1, measles+mumps, measles+rubella, Influenza, Diphtheria, Tetanus Toxoid, Pertussis, Mumps, Rubella and DT and OPV, CRM 197,
12	Shantha Biotechnics	DTP, DTP+HepB+Hib, DTP+Hib, DPT+Hep B, Tetanus Toxoid, Hib, Hep-B, DT, Hib, Hep B, RTF, Oral cholera, IPV RTF Bulk, IPV, Inact. B. pertussis
13	GSK Asia Pvt. Ltd	Pneumococcal Polysachharide and Non-Typeable Haemophilus influenza
14	Sanofi Pasteur, India Pvt Ltd	Hib, DTP-Hib, Typhoid, Hep A, Pneumococcal, Yellow fever, seasonal influenza, rabies, meningococcal, IPV, DTaP-IPV-Hib, Varicella, DTaP

Source: Industry, Anand Rathi Research

Appendix

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