

PHARMACEUTICALS

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Takeaways from Pharma expert call

We hosted Dr. Deepak Hedge, Chief Technology Officer, EOC Pharma – Shanghai, as part of Pharma expert series (Virtual) last week. Earlier, he has headed product development and outsourcing at GSK's Shanghai R&D (2014-19) for its global portfolio. With a relevance to India potential, the call provided deeper insight across Covid vaccine programs, Global supply disruption in KSM/API space, Progress on China +1 strategy by global pharma, and Future R&D investments. Below are the key highlights.

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Supply disruption in KSM/API and China dependence: India missed a big opportunity by not being ready to replace China during the Covid pandemic especially in antibiotic to EU/US. US imports of antibiotic from China is highest (Ibu 95%, hydrocortisone 91%, acetaminophen 70%). PLI scheme is right step to self-reliant India but unlikely to grab any meaningful benefit for listed players given China supplies has scaled up substantially post Aug'20. India is <4% share of the Global market vs. 15%+ for Chinese CRAMS companies.

Covid vaccine – Upside for Indian players too early to ascribe: Distribution of Pfizer & Moderna vaccine (efficacy 95%, stored at -20 to -70 degree) in India appears non-viable in view of inadequate cold chain infrastructure. Mass-scale vaccination may uncover adverse events. Indian regulators could play safe on Indian vaccines (Cadila, Bharat bio, Serum, Dr. Reddy's – launch planned around Mar'21) as these are never being approved by any major regulators. Hence, upside from launch is too early to ascertain ([Fig 1: Key vaccine assets](#)).

China +1 strategy reality: Demand for alternate supply source from Global Pharma is largely visible in the Innovators CDMO model compared to generics. Security/quality of supply are critical over cost arbitrage in choosing CDMO partner. Expert highlighted, amongst the CROs Syngene & Jubilant Life are strong choice by innovators while Divi's brings cost advantage, quality and scale.

Future R&D focused around cell and gene therapies: Globally, R&D portfolios of big pharma have shifted over last 10 years. Presently, small-molecules accounts for 60% while biologics 40% - expect that a 50:50 structure is possible to continue in the foreseeable future. Innovations around cell and gene technology to treat severe diseases is picking pace.

...(continued in next page)

RECOMMENDATION SNAPSHOT

Ticker	Rating
AJP IN	BUY
ALKEM IN	BUY
ALPM IN	BUY
ARBP IN	BUY
CIPLA IN	BUY
DIVI IN	ADD
DRRD IN	ADD
ERIS IN	BUY
LAURUS IN	BUY
LPC IN	ADD
SUNP IN	ADD



For example, CAR-T cell therapy to treat cancer is seeing lot of R&D interest and investments besides developing long acting injectables. CAR-T therapy cost ~US\$ 1-1.5mn in US and India could play key role in driving down the cost.

China generic opportunity is intact: China 4+7 tender trial for volume based procurement (VBP) has widely evolved and VBP value of US\$ 8bn in 3rd national scale tender round (happened in Aug'20) has doubled compared to previous two rounds. The average price cut (per unit versus each molecule's ceiling price) was 72.2%. Remain optimistic on China generic opportunity over next 5 years given better pricing scope in differentiated generics vs. pain vanilla products.

India turning into tender market far-fetched: Risk of India pharma shifting to tender based market is far-fetched due to lack of reimbursement market. Influx of online pharmacy and Janaushadi are unlikely to impact established India players as online pharmacy are heavily dependent on branded generics and Janaushadhi stores has poor quality perception. China before adopting 4+7 tender policy made Generic Quality Consistency Evaluation (GQCE) mandatory for all products which ensure quality equivalence.

Other Takeaways

- Expressed great confidence in the management of Sun Pharma & Dr. Reddy's when it comes to taking tough & quick decisions. India should learn from China regarding luring Chinese talent back home from the US, Europe & other developed nations.
- Common infrastructure provided by the government, free trade zones & facilities to ship products overnight to countries like the USA make China more efficient compared to the India.
- Fermentation capacity expansion in antibiotics is a costly affair from EHS view point while it poses a good opportunity for products other than antibiotics.
- Logistical and Regulatory challenges make it difficult for the Market to respond to disruption. Securing a Fully operational alternate supply chains for drugs can take anywhere from 9-24 months.
- The key drug classes where APIs are imported in large quantities from Chinese suppliers are 1) Antibiotics, 2) NSAIDs, 3) ARVs, 4) Anti-epileptic, and 5) basic cancer products.
- The KSMs that are imported from China are 1) Acetic acid, 2) Para Amino Phenol, 3) 6 APA, 4) Adenine, and 5) Pen G.

- About 70% of APIs evolve from China to the rest of the world. China accounts for 95% of US imports of ibuprofen, 91% of US imports of hydrocortisone, 70% of US imports of acetaminophen, 40% to 45% of US imports of penicillin, and 40% of US imports of heparin. In total, 80% of the US supply of antibiotics is made in China.
- Apprehensions about vaccines being developed by China & Russia is due to lack of transparency in disclosing data.

FIG 1 – LEAD VACCINES CANDIDATES

Developer	Type	Phase	Status
Outside India			
Pfizer BionTech BNT162b2	mRNA	2, 3	Approved in UK, Canada. Emergency use in US and some other countries. Efficacy: 95%, Dose: 2 doses, 3 weeks apart, Storage: Freezer storage only at -94°F (-70°C)
Moderna, mRNA-1273	mRNA	2, 3	Under FDA Review, Efficacy: 94.5%, Dose: 2 doses, 4 weeks apart, Storage: 30 days with refrigeration, 6 months at -4°F (-20°C)
CanSino, Ad5-nCoV	Adenovirus	3	Limited use in China. Efficacy: Unknown, Dose: Single dose, Storage: Refrigerated
Gamaleya, Sputnik V (formerly Gam-Covid-Vac)	Adenovirus	3	Early use in Russia, Efficacy: 91.4%, Dose: 2 doses, 3 weeks apart Storage: Freezer storage. Developing alternative formulation that can be refrigerated.
J&J, Ad26.COVS.2S	Adenovirus	3	Efficacy: Unknown, Dose: 1 dose Storage: Stable in refrigerator
Oxford-Astrazeneca, AZD1222	Adenovirus	2, 3	Efficacy: Up to 90, Dose: 2 doses, 4 weeks apart Storage: Stable in refrigerator for at least 6 months
Vector Institute, NVX-CoV2373	Protein	3	Early use in Russia
Novavax	Protein	3	Efficacy: Unknown Dose: 2 doses, 3 weeks apart Storage: Stable in refrigerator
Sinopharm Beijing BBIBP-CoV	Inactivated	3	Approved in Bahrain, UAE, Limited use in China Efficacy: 86% Dose: 2 doses, 3 weeks apart,
Sinopharm Wuhan	Inactivated	3	Limited use in China, UAE
Sinovac, CoronaVac	Inactivated	3	Limited use in China, Efficacy: Unknown, Dose: 2 doses, 2 weeks apart Storage: Refrigerated
India			
Zydus Cadila	DNA based	3	Phase 3 to start in Dec'20. Distribution expected by Mar 21
Gamaleya, Sputnik V (formerly Gam-Covid-Vac)	Adenovirus	3	Phase 3 data reviewed by India, Dr. Reddy's to conduct Phase 3 trial in India, Efficacy: 91.4%, Dose: 2 doses, 3 weeks apart Storage: Freezer storage. Developing alternative formulation that can be refrigerated.
Oxford-Astrazeneca, Covishield	Adenovirus	2, 3	Emergency use authorization applied by Serum India was rejected by DCGI. Efficacy: Up to 90%, Dose: 2 doses, 4 weeks apart Storage: Stable in refrigerator for at least 6 months
Bharat Biotech (collaboration with the ICMR and National Institute of Virology, Covaxin	Inactivated	3	Approval for emergency use rejected for additional data. Distribution by June'20 Efficacy: Unknown, Dose: 2 doses, 3 weeks apart Storage: At least a week at room temperature

Source: BOBCAPS Research

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ADD – Expected return from >+5% to +15%

REDUCE – Expected return from -5% to +5%

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