Reclaiming SAARC from the ashes of 2020

Bottom line: Despite the despondency, the rationale for its existence is intact, and India can use it as a stage for its global ambitions

Losses of a dead SAARC

1. The World deals with South Asia as a fragmented group rather than a collective, working with each country in separate silos or in smaller configurations.
2. SAARC initiatives on connectivity and trade suffer
3. Reviving SAARC is crucial to countering the common challenges brought about by the pandemic. The pandemic's impact on South Asian economies is another area that calls for coordination.
4. Apart from the overall GDP slowdown, global job cuts which will lead to an estimated 22% fall in revenue for migrant labour and expatriates from South Asian countries.

World Bank Case Studies

World Bank reports that have estimated the losses have all suggested that South Asian countries work as a collective to set standards for labour from the region, and also to promoting a more intra-regional, transnational approach towards tourism, citing successful examples including the 'East Africa Single Joint Visa' system, or similar joint tourism initiatives like in the Mekong region or the Caribbean islands.

A time for regional initiatives

1. In the longer term, there will be a shift in priorities towards health security, food security, and job security, that will also benefit from an "all-of" South Asia approach.
2. The impact of COVID-19 will be seen in broader, global trends: a growing distaste for 'globalisation' of trade, travel and migration, as well as a growing preference for nativism, self-dependence and localising supply chains.
3. While it will be impossible for countries to cut themselves off from the global market entirely, regional initiatives will become the "Goldilocks option" (not too hot and not too cold), or the happy medium between globalisation and hyper-nationalism.
4. It would be important to note, therefore, that as the world is divided between regional trade arrangements, India's only regional trading agreement at present is the South Asian Free Trade Area, or SAFTA (with SAARC countries).

Existing Regional Agreements

United States-Mexico-Canada Agreement, or USMCA	North America
Southern Common Market, or MERCOSUR	South America
European Union	Europe
African Continental Free Trade Area, or AfCFTA	Africa
Gulf Cooperation Council, or GCC	Gulf
Regional Comprehensive Economic Partnership, or RCEP	South-East Asia and Australasia including China

China's quest

1. In dealing with the challenge from China too, both at India's borders and in its neighbourhood, a unified South Asian platform remains India's most potent countermeasure.
2. At the border, it is clear that tensions with Pakistan and Nepal amplify the threat perception from China, while other SAARC members (minus Bhutan), all of whom are Belt and Road Initiative (BRI) partners of China will be hard placed to help individually.
3. Despite the rebuff, China has continued to push its way into South Asia, as several statistical indicators for investment, trade, tourism and South Asian student preferences for universities.
4. Experts suggest that it is only a matter of time before Beijing holds a meeting of all SAARC countries (minus India and Bhutan), for they are all part of the BRI, and even that they will be invited to join RCEP, which India declined.

India's steps, more bilateral

1. In contrast, India stepped up its health and economic diplomacy in the region, but apart from one SAARC meeting convened by Mr Modi in March, these have been bilateral initiatives, not a combined effort for South Asia.
2. These are some of the reasons that led all SAARC leaders other than Mr Modi to urgently call for the revival of SAARC during their charter day messages.

Despite the despondency, the rationale for its existence remains intact:

1. While history and political grievances may be perceived differently, geography is reality.
2. Seen through Beijing's prism, India's SAARC neighbourhood may be a means to contain India.
3. New Delhi must find its own prism with which to view its South Asian neighbourhood as it should be: a unit that has a common future, and as a force-multiplier for India's ambitions on the global stage.

The debilitating side-effect of a flawed vaccine trial

HPV vaccine trial controversy

1. Human papillomavirus (HPV) vaccine was controversial and carried out without proper consent
2. Back then the Supreme Court of India slammed the government for slipping into "deep slumber" in addressing the "menace" of illegal clinical trials carried out in India by multinational countries, nothing much seems to have changed.

Covaxin

1. The phase-3 clinical trial of Bharat Biotech's COVID-19 vaccine, Covaxin, by a private hospital in the Bhopal-based Peoples College of Medical Sciences & Research Centre appears to suffer from serious violations.
2. Incidentally, the ICMR, tasked with promulgating research ethics guidelines, is the co-sponsor of the Covaxin trial.

Many missteps

1. The Covaxin trial participants alleged that they were ignorant of what they were signing up for. If true, it amounts to a violation of informed consent clause.
2. The participants were not made aware of their rights to free medical care in case of any adverse events.
3. The Trial participants have told the media that they were lured with monetary benefits of ₹750. Luring people to participate in clinical trials by offering money is unethical.
4. In the case of serious adverse events following injection with AstraZeneca's COVID-19 vaccine in a trial outside India, the information was made public, and the trial was halted at all sites while an investigation was underway. The Serum Institute was also ordered to halt the trial by the Indian regulator pending investigation.

New Rules not followed

1. Following the October 2013 Supreme Court order, the Indian regulator had in 2019 made mandatory an audio-video recording of the informed consent process of each vulnerable individual participant before conducting clinical trials. And a written consent from the participant had to necessarily be taken before the audio-video recording of the informed consent process.
2. There is no evidence that this was followed, based on what the participants said during the press conference.

Conclusion

Only a thorough and impartial probe will restore confidence in clinical trials.

Background:

India a prefered destination for clinical trials

Drug companies are drawn to India for several reasons, including a technically competent workforce, patient availability, low costs and a friendly drug-control system. While good news for India's economy, the booming clinical trial industry is raising concerns because of a lack of regulation of private trials and the uneven application of requirements for informed consent and proper ethics review.

The key Issues regarding Clinical Trials

1. According to submission in Supreme Court, about 2,800 patients have died in India during 2005 and 2012, while participating in clinical trials conducted by pharmaceutical companies.
2. It has been found that people from low-income groups are over-represented in clinical trials. Companies exploit people who are in need of money and the people who are ignorant of the medical consequences of the trial.
3. The regulatory system to oversee clinical trials have serious backdrops. The members in the committees formed for the approval process lacks adequate experience and qualification and have a conflict of interest. Also, there is no check on the functioning of ethics committees. Further, the regulatory process is considered to be slow, hence delaying the process of drug development.
4. A very unethical practice being followed is that- usually the consent of the participants in the clinical trials is not taken.
5. The Clinical Trials Registry formed under the Indian Council of Medical Research calls for registration of all clinical trials conducted in India. However, there is a very poor registration rate. Resultantly, the data about various trials is inaccessible or even not published at all due to "negative" results.

Clinical Trials in India are governed by the following laws and regulations:

1. The Drugs and Cosmetics Act, 1940 and the accompanying Drugs and Cosmetic Rules, 1945 which are revised from time to time. These rules mandates that clinical trial is conducted as per the Good Clinical Practices (GCP) guidelines issued by the Central Drugs Standard Control Organisation (CDSCO).
2. Indian Council of Medical Research as the apex regulatory body for clinical trials.
3. The Supreme Court order in 2013 which has set up a three-tier review process.

The steps taken by the government in this regard

1. It has been made mandatory to register at the Clinical Trials Registry-India. This will improve transparency, accountability and accessibility of data related to clinical trials.
2. The Drugs Controller General of India has mandated audio-visual recording and safe storage of the consent taking the process from participating individuals.
3. A recent amendment to the Drugs and Cosmetics Act requires compensation to be paid in respect of Serious Adverse Events (SAEs) of death attributable to clinical trials.