Bridge this deficit between India and Sri Lanka

The announcement by Sri Lanka's President Ranil Wickremesinghe, recently, about a proposal to establish land connectivity with India has come none too soon. Twenty years ago, in Chennai, Mr. Wickremesinghe, then Prime Minister, while delivering a lecture, floated the idea of building a bridge linking Rameswaram in Tamil Nadu with Talaimanar in the Northern Province of Sri Lanka. This was part of his larger vision of regional economic integration, encompassing his country and the southern States of India and aimed at generating more opportunities for economic growth.

He has been discussing the concept of economic integration on many an occasion and at several international fora. But, whenever groups and parties claiming to represent the interests of Sinhalese-Buddhists expressed their opposition to the proposal on the ground that this would not benefit Sri Lanka, the talk of having expanded physical connectivity would die down. In December 2015, when India's Road Transport and Highways Minister Nitin Gadkari informed the Lok Sabha that the Asian Development Bank was willing to fund the bridge project of ₹24,000 crore, Sri Lanka's response was muted followed by sharp criticism from the project opponents.

However, to the credit of Mr. Wickremesinghe and Prime Minister Narendra Modi, the idea of land connectivity was not abandoned. It found a mention in a joint statement issued in July after the two leaders met in New Delhi. The document even stated that "a feasibility study for such connectivity will be conducted at an early date." As a follow up, Mr. Wickremesinghe, who is also Finance Minister, in his Budget address on November 13, referred to the project of land connectivity and and said "we expect to utilise Colombo port to meet the supply needs of south west India and Trincomalee port to meet the supply needs of south east India".

The case of a power grid

But, the relationship between the two countries in the area of infrastructure development should have been much deeper than what it is. For example, the idea of connecting the electricity networks of the two countries was floated even in 1970.

T. Ramakrishnan

The relationship between India and Sri Lanka in the areas of infrastructure development, energy links and trade should be much deeper than what it is now

Over 13 years have lapsed since the two countries signed a memorandum of understanding on the bilateral grid, but not even one unit of electricity has been transmitted. In the case of Bangladesh, India has been exporting at least 7,000 million units (MU) annually for the last couple of years. About a month ago, Mr. Modi and Bangladesh Prime Minister Sheikh Hasina jointly commissioned, in virtual mode, the second unit of the Rampal Maitree Power Project (660 megawatt), apart from launching two other infrastructure projects. In fact, Sri Lanka and Bangladesh had inked memoranda of understanding with India in the same year (2010) for collaboration in the power sector.

It is not that no energy projects are being taken up by the former, as there are certain projects underway involving Indian participation in the energy sector, particularly renewable energy. Besides, the island-nation needed time to recover from the protracted civil war of 25 years. Yet, the progress of the transmission network project, envisaging the transfer of 1,000 MW and the establishment of a High Voltage Direct Current overhead link between Madurai (India) and New Habarana (Sri Lanka), does not reflect well on the two countries. Had the facility been in place in 2022, Sri Lanka would not have suffered power cuts and blackouts then. A day may come when India will be able to source cheaper power from Sri Lanka. The two countries should be focused to ensure that the deadline of 2030 is met.

On trade

Energy is not the only area where progress has been tardy. The India-Sri Lanka Free Trade Agreement was signed in December 1998, yet the two countries have not yet been able to go beyond it despite holding talks for years on entering into an economic and technology cooperation agreement. After a break of five years, negotiations resumed a few weeks ago.

Notwithstanding several constraints, even now, bilateral economic ties seem to be on better footing with India regaining its position last year as the largest source of imports and accounting for about 26% of total imports of Sri Lanka, though certain portions of imports were through credit lines offered by India in the wake of the economic crisis. In the area of tourism, which is a major source of revenue for Sri Lanka, India remained the largest single country of tourist arrivals, with its share being 17% of the overall number of arrivals. But, the potential is much higher and the underperformance of Sri Lanka is telling, going by India's bilateral trade in 2021 with its southern neighbour and Bangladesh, whose recent economic growth has been impressive. The size of the former was $5.45 billion in 2021 whereas that of the latter was $18.14 billion.

A start has been made

Sri Lanka, which has a long track record of the incumbent government ensuring the smooth transition of power to its successor after electoral defeat, should not be bogged down in the baggage of history. The presence of anti-Indian nationalist forces in the political class is nothing unique to this country. Still, Bangladesh has shown the way to have a mutually-beneficial economic relationship.

In fact, with respect to Sri Lanka, the momentum generated by certain developments in the last one year (resumption of air services between Chennai and Jaffna, the launch of passenger ferry services between Nagapattinam and Kankesanthurai and a joint venture agreement among India's National Dairy Development Board, the Gujarat Cooperative Milk Marketing Federation and Cargills of Sri Lanka for self-sufficiency in the dairy sector) should be sustained and improved upon. There is every reason why Sri Lanka, once viewed as a high standard of living and stable economy, should be keen on making this a reality.

ramakrishnan.t@thehindu.co.in

India's alarming 'fixed dose combination' problem

A group of academics from India, Qatar and the United Kingdom recently published a worrying new study in the *Journal of Pharmaceutical Policy and Practice* (2023, 16:39) on the volume of unapproved and even banned fixed dose combination (FDC) of antibiotics that are being sold in India. Using sales data of the pharmaceutical industry, the study documents that in the year 2020, 60.5% FDCs of antibiotics (comprising 239 formulations) were unapproved and another 9.9% (comprising 39 formulations) were being sold despite being banned in the country. That so many of these unapproved or banned FDCs contain antibiotics is alarming because of the increasing prevalence of antibacterial microbial resistance (AMR) in India.

FDCs are combinations of one or more known drugs and can be useful in the treatment of some diseases since the combination can improve patient compliance. For instance, if a patient has to take three different medications for a particular treatment, she may forget to take one. But if all three medications are combined into one tablet or one syrup, the chance of her forgetting to take one or two of the drugs is reduced. For diseases such as AIDS, it is well documented that FDCs have proven to be very useful in improving patient compliance, which at the end of day improves treatment outcomes.

Making FDCs, even though most consist of drugs with known safety and efficacy profile, is not an easy job. All drugs have side effects and when formulated together, there is a possibility that the active ingredient or even the excipients (inactive ingredients) may affect the way that each drug functions. For example, the drugs may interact in a way to reduce the therapeutic efficacy of each active ingredient, or, worse, the drugs may interact with each other to create a more toxic element, often called metabolites. This is why it is crucial that all FDCs go through a scientifically designed approval process where such interactions can be evaluated.

The pharmaceutical industry's love for FDCs

Pharmaceutical companies in India use these FDCs to escape liability under multiple laws without much concern for public health. One such law is the Drugs (Prices Control) Order (DPCO), under which the government fixes the prices of individual drugs. Since drug combinations were traditionally not covered under the DPCO, the pharmaceutical industry decided that making FDCs provided an easy way to escape the remit of the DPCO.

Dinesh Thakur
is the co-author of 'The Truth PIL: The Myth of Drug Regulation in India' (2022)

Prashant Reddy T.
is the co-author of 'The Truth PIL: The Myth of Drug Regulation in India' (2022)

That many of these unapproved or banned FDCs contain antibiotics is cause for concern given the growing antibacterial microbial resistance in the country

Driven by this cold logic of the market, and not public health, the Indian pharmaceutical industry introduced an astounding variety of FDCs that lacked any medical rationale. For example, anti-inflammatory drugs were combined with vitamins, anti-histamines were combined with anti-diarrhoeal agents, penicillin was combined with sulphonamides, and vitamins were combined with analgesics. These were combinations not found in any other country.

There were two added advantages of adopting this strategy for the industry. The first, the fact that because of the bewildering variety of FDCs being sold in the market, there were no standards set by bodies such as the Indian Pharmacopoeia Commission for testing these drugs for quality of manufacture. When there are no standards recognised by the law, there is no question of manufacturing "not of standard quality" drugs, and hence there is no possibility of prosecution under the Drugs & Cosmetics Act, 1940. At most, when these FDCs are sampled in the market and sent for testing, the usual protocol for government laboratories conducting such tests is to write to the manufacturer and ask for their own protocols to test the drug. In other words, the pharmaceutical industry gets to provide its own standards in order for the government to test their drugs.

The second advantage of going down the FDC route is that it gives individual companies a reason to charge higher prices for their drugs. For example, if 20 different pharmaceutical companies were manufacturing and selling a drug such as azithromycin, they would have to compete furiously and reduce prices to capture a larger share of the market. But if they combine azithromycin with another drug, for example, cefixime to create a FDC, they can claim it as a new unique product catering to a specific need, thereby allowing them to charge a higher price until others introduce similar products, at which point the first mover may try to create a new FDC. When the market and the regulatory structure rewards these manufacturers of such pseudo-innovation rather than for discovering and developing true innovative medicines, this is what happens. These dubious FDCs can command higher prices. Of course, none of this is possible without doctors who are willing to prescribe such FDCs. While it is tempting to paint all such doctors as corrupt, the fact of the matter is that most doctors wrongly presume that the drug regulator is doing its job when a product is sold on the market.

The FDC problem has been on the regulatory radar since 1978 when the first government committee studied the issue and admitted that we had a problem on our hands. At the time, there was no system under the colonial-era Drugs and Cosmetics Act, 1940 to vet drugs for safety and efficacy prior to their sale in India. This meant that each State drug controller could hand out manufacturing licences for any drug formulation and there was little that the central government could do to stop their sale.

In 1982, Parliament changed the law to give the central government the power to "prohibit" the manufacture of specific drugs that lack therapeutic value or justification. Later in that decade, in 1988, the central government amended the rules to introduce a new requirement for manufacturers of all "new drugs", including FDCs, to submit proof of safety and efficacy to the Drugs Controller General of India (DCGI) who heads the Central Drugs Standard Control Organization (CDSCO). These amendments also made it clear that State drug controllers could not grant "manufacturing licences" for "new drugs" that are not approved for safety and efficacy by the DCGI.

Unabated licensing

Despite the law being crystal clear on the issue, State drug controllers have simply ignored the law to continue issuing manufacturing licences for FDCs not approved by the DCGI with impunity. The manufacturers selling these FDCs that have not been approved by the DCGI can technically be prosecuted by the Central government for violating the law.

Instead of ordering criminal prosecutions, the Ministry of Health is playing a game of whack-a-mole by constantly invoking its powers under Section 26A to prohibit the manufacture of specific FDCs. It has issued 444 orders under this provision since 1983, banning mostly FDCs. Many of these orders have been embroiled in complex litigation, with the courts muddying the waters with inconsistent decisions.

The fact that these academics have discovered 239 unapproved FDCs being sold in 2020 in just one category of FDCs (their previous studies have revealed similar unapproved FDCs in other therapeutic categories), more than 42 years after the problem was first flagged is an astonishing indictment of the incompetence of the drug regulatory framework in India. As they point out in their paper, unregulated FDCs may end up contributing to the AMR problem in India. It is vital for the Ministry of Health to take immediate action.