



Wealth and wellness regulation: A contrast

The regulators of wealth in India are empowered and autonomous, unlike the regulators of wellness, leading to very different outcomes in the two sectors

Regulation is a form of state intervention to correct market failures. Though we see this very visibly in finance, this approach to regulation is not restricted to the financial sector. State intervention is necessary when the free market yields inefficient and poor outcomes. Regulation usually involves creation of arm's length statutory authorities that are empowered and autonomous.

The Reserve Bank of India (RBI) regulates banking and payment systems and conducts monetary policy, autonomously and at a distance from political considerations that are likely to influence actions of the Ministry of Finance. Likewise, unlike its predecessor, the Controller of Capital Issues (CCI), the Securities and Exchange Board of India (Sebi) regulates the securities market not from the North Block but from the Bandra Kurla Complex in Mumbai. Similar is the case with other Indian "wealth" regulators. As a result, the financial sector is much better regulated than it was when the government directly regulated the sector.

This happy outcome did not just happen. The implementation of recommendations of expert committees and parliamentary oversight led to changes to keep up with evolving domestic developments and the global best practices. That's not to say that regulatory reforms in finance are complete. The continuing problems of consumer protection and technological developments, like fintech, call for revisiting these issues periodically. The last comprehensive report was of the Financial Sector Legislative Reforms Commission (FSLRC), which made holistic recommendations to strengthen regulatory autonomy and accountability.

The health sector, much like the financial sector, is fraught with potential market failures. However, it is an incredibly complex sector — perhaps more than finance — and health policy is one of the most difficult areas of public policy. Within the health sector, the field of public health is usually marked by two kinds of market failures — externalities and provision of public goods. Healthcare, on the other hand, is normally characterised by information asymmetry and market power. Unlike in finance, "regulation" by an authority need not necessarily be the right answer in health given its complexity. This article looks at health sector regulation as it exists now and proposes improvement in the manner of regulation.



**AARTHIKAM
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K P KRISHNAN

The Constitution of India allocates the subject of health to both the Union and states. Focusing only on the Union, India has a statutory regulatory authority for setting and enforcing standards for food safety and one non-statutory authority for safety of drugs and pharmaceuticals and one for regulating the prices of some of them.

Given the very skill-intensive nature of healthcare, the regulation of the wellness sector necessarily involves regulating health sector professionals. We, therefore, have an authority each for regulating the medical, dental nursing and pharmacist professions. Recently a regulator has been created for allied health care professionals like physiotherapists, optometrists and over 50 other professionals who support diagnosis and treatment. In addition, there is a separate regulator for rehabilitation professionals like speech therapists, clinical psychologists, hearing aid and ear-mould technicians; special

teachers for educating and training the handicapped and so on. That makes it nine national regulators for the "wellness" sector.

Despite this large presence of regulators, *prima facie* most observers would agree that regulation of the Indian financial sector appears to be better than the regulation of our wellness sector. Recent reports of exports of sub-standard paediatric drugs and the last two years of the pandemic experience have brought home to us the importance of and the not-so-happy state of "regulation" of the Indian health and the wellness sector. Why is this so?

Regulation is a difficult and heavy-handed form of state intervention. The big lesson from years of financial sector regulation in India is that traditional government departments are ill-suited to do this. Regulation is best done by well-designed statutory authorities that are autonomous and empowered and accountable for outcomes. Autonomy and empowerment of regulators essentially require two design features. The first is the power and ability to write enforceable regulations for the domain. The second is access to financial and human resources to enforce regulations without fear or favour.

In the wellness sector, like in the financial sector of the early 1990s, it is the Ministry of Health that continues to be the primary regulator. For example, the law on drugs and the law on clinical establishments empower the Ministry of Health and not an arm's length statutory agency.

Uniformly, without exception, financial sector regulators are empowered by law to write regulations to carry out the purposes of the law. When Sebi was created, the law required regulations made by Sebi to be approved by the Ministry of Finance. In the first amendment to the Sebi Act, this was deleted. In contrast, eight of the nine regulators in the wellness sector need government approval for issuing regulations. The one exception is the National Medical Commission (NMC) created in 2019 to replace the Medical Council of India.

The other elements of effective regulation, namely access to human and financial resources required to discharge onerous regulatory functions are almost entirely missing in the design of wellness regulators. The governing boards of all the financial sector regulators have the power to determine the human resources required by them as well as the terms and conditions of employment of these human resources. None of the wellness regulators have these powers and need government approval for such decisions.

This needs to change and regulatory design in the wellness sector needs to be on the lines of the sector-agnostic recommendations on "regulatory governance & accountability" of the FSLRC. Similar is the position on access to adequate financial resources.

We made an important beginning in this sector with the creation of the NMC and a regulator for allied health care professionals. A new piece of legislation to replace the legal framework for drugs and pharmaceuticals (including medical devices) is in the works. Let alone being empowered, the regulator for drugs is not even mentioned in the (old or) new draft law. Regulation of wellness deserves much greater attention from scholars, policy-makers and the parliament.

The writer is an honorary professor at the Centre for Policy Research, member of a few for-profit and not-for-profit boards, and a former civil servant