

COMMENTS

Science, Technology and Innovation Policy 2013: whither innovation and inclusion?

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India is one of the pioneering countries in the developing world that explicitly recognised the key role of science and technology in addressing problems of development. Jawaharlal Nehru, the prime architect of modern India, while addressing the Indian Science Congress in 1938, stated that science alone could solve the problems the country faced: hunger and poverty, insanitation and illiteracy, superstition and deadening custom and tradition.

However, despite the scientific and technological achievements in diverse fields like atomic energy, space, defence, information technology, and pharmaceuticals, there is abject poverty and growing inequality at different levels in India. These coexist with higher Gross Domestic Product (GDP) growth under globalisation. Pandit Nehru's concerns of 1938 still remain, despite policy pronouncements about harnessing science and technology for development, and multitude of policy measures to address poverty and achieve equity. India has built a national innovation system as a conduit for growth, but as the resultant growth has not been inclusive, it may be inferred that the system of innovation has not been inclusive. Against this background, and with a heightened concern for inclusive development articulated in the recent Five Year Plans, the Science Technology and Innovation Policy (STIP), 2013(1), presents a new paradigm highlighting the role of innovation in fostering inclusive development.

New paradigm in perspective

The science and technology paradigm for India was laid down by the Science Policy Resolution (SPR) passed by the Indian Parliament in 1958. This underlined the need to pursue self-reliance in technology: "in industrialising a country, heavy price has to be paid in importing science and technology... An early and large scale development of science and technology in the country could therefore greatly reduce the drain on capital during the early and critical stages of industrialisation." Hence the SPR aimed "to foster, promote, and sustain, by all appropriate means, the cultivation of science, and scientific research in all its aspects – pure, applied and educational" (4).

The need to achieve self reliance was reinforced when the first comprehensive science and technology plan (1974-79) was formulated and integrated with the Fifth Five Year Plan. The agenda of self reliance was taken forward with the Science Policy Statement of 1983 and subsequently by the Science and Technology Policy of 2003. The former aimed at achieving technological competence and self reliance.

The latter emphasised the need for investment in research and development (R&D) and integrating programmes of the economic and social sectors with national R&D, which involves building a national innovation system.

STIP 2013 states that "Science, technology and innovation for the people" is the new paradigm of the Indian science technology innovation (STI) enterprise (1). The new policy is refreshing in its call to integrate the process of innovation with science and technology, and make innovation inclusive as a means of fostering inclusive growth.

The policy calls for a framework to enable the integration of innovation with science and technology in identified priority areas. It also states that "new structural mechanisms and models are needed to address the pressing challenges of energy and environment, food and nutrition, water and sanitation, habitat, affordable healthcare and skill building and unemployment." (1:3) The policy acknowledges that innovation for inclusive growth implies "ensuring access, availability and affordability of solutions to as large a population as possible" (1:3).

However, a careful examination of the document reveals that it neither articulates an inclusive innovation system, indispensable for generating inclusive development, nor locates the varied spaces of exclusion that have emerged over time. The inevitable outcome is that the policy fails to move from the paradigm to a credible trajectory; and that innovation for inclusion remains, at best, just rhetoric.

Innovation: confusion compounded?

The national innovation systems perspective has emerged as the most widely used approach in innovation studies published during the last two decades (5). According to this perspective, the development of an economy is shaped by its underlying innovation system. It has also been argued that the innovation systems approach is eminently suited to understanding the role of innovation in developing countries (6). Here innovation, following Schumpeter's work in 1961 (7), is not confined to new products and processes; it includes new markets, new organisations and, in general, new ways of doing business in which institutions play an important role.

Innovation involves a non linear process of learning through interaction between different actors and networks -- the

network of R&D organisations and universities is only one among many networks -- leading to competence building at various levels. Innovations and institutions must "co-evolve", in tune with the changing socio-economic context. An innovation system is construed not only at the national level; it also exists at the sectoral/ sub-sectoral, regional/sub-regional levels and at the level of different technologies. And since innovation breeds development, if development is to be inclusive, the underlying innovation system must be inclusive. The nature of interaction and the co-evolution of institutions and innovations guarantee an inclusive innovation system.

The new policy calls for the creation of a robust innovation system. Its vision is to accelerate the pace of discovery and delivery of science-led solutions for faster, sustainable and inclusive growth. Here, innovation is viewed on par with R&D, just like GDP growth with development; it ignores the fact that in developing countries like India, R&D is only one of the factors that shape innovation and development. Besides innovation, the commercial application of an invention, is conceived as just one stage in a linear process of technological change that involves invention, innovation and diffusion. Innovation is expected to induce growth through its diffusion which is driven mainly by the market. But innovation driven by demand does not guarantee inclusive development. This is particularly so because the users of such technology are passive adopters with hardly any role either in invention or innovation. This is evident when the policy states, for example, "NGOs will be accorded a pivotal role in the delivery of STI output, especially rural technologies to the grass root level". This perspective makes NGOs passive recipients and not active partners in the innovation process.

The new policy upholds the need for doubling the Gross Expenditure in Research and Development to two per cent of GDP. This has been a national goal for some time. The new policy envisages achieving this goal with greater reliance on private sector R&D, *inter alia* through the establishment of large R&D facilities in the public-private partnership mode, treating R&D in the private sector on par with public institutions for availing of public funds, and providing incentives and modifying the intellectual property rights system. The policy also calls for strengthening of science education, setting up of inter-varsity centres, identification of sectors with high impact potential, participation in global R&D infrastructure, and performance-linked incentive schemes.

Initiatives such as the target of doubling the R&D effort are laudable and necessary for inclusive development. What is missing is an articulation of an inclusive innovation system that facilitates interactive and socially embedded learning and a competence building process -- at the regional/sub-regional, sectoral/sub-sectoral levels and at the level of different technologies. Such an approach could have helped to address the pressing needs rightly identified by the policy. Here it may be noted that the strategy paper by the Office of the Adviser to the Prime Minister, Public Information Infrastructure and Innovations, 2011 (8), has addressed some of these issues. Hence,

the new policy while claiming to bring fresh perspectives turns out to be a step backwards, not forward.

Inclusion: only in rhetoric?

In order to achieve inclusive development, apart from evolving an inclusive innovation system, there is also a need to locate and address the varied types of exclusion that have emerged over time. This is all the more important when there is hardly any consensus on the credibility of the widely used indicators of poverty and inequality. Here Amartya Sen's taxonomy of social exclusion is illuminating (9). Sen considers four situations: (i) constitutive exclusion occurs when being excluded is in itself a deprivation of intrinsic importance; (ii) instrumental exclusion refers to causally significant exclusions that may not be impoverishing by themselves, but can lead to impoverishment of human life through consequences of great instrumental importance; (iii) active exclusion happens when exclusions come about through policies directly aimed at that result; (iv) passive exclusion is the result of policies that have not been devised to bring about that result but nevertheless have such consequences.

Viewed in terms of the nature of outcome, we could also have sustained exclusion vs transient exclusion. Very often, unbalanced development strategies (10) involve a degree of exclusion of some sectors/sections for some time. This may be termed as "transient exclusion". However, if the excluded remain excluded for long periods, we have cases of "sustained exclusion" which is socially more oppressive. We could also have "subordinated inclusion and illusive inclusion" depending on how the inclusion takes place and how the returns of inclusion are distributed. The former occurs when inclusion takes place in such a way that its gains are not equally distributed. "Illusive inclusion" occurs when inclusion is ensured but the outcome is not different from that of being excluded. To the extent that those included hardly derive any benefits, inclusion is illusive (11).

If inclusive development is a goal of the STI policy, it should have been backed by an understanding of the existence and consequences of the varied forms of exclusion in our innovation system; it should have unequivocally addressed them as part of its articulation. In the absence of any serious effort towards either identification or mitigation of different forms of exclusion, the call for gender parity and establishment of a fund for innovations for social inclusion appears to be sheer rhetoric.

Innovation has been a valuable "cheque" for the poor, helping to lift millions of people across the world out of poverty. But given the costly silence of the new policy regarding the varied spaces of exclusion, and its inability to articulate an inclusive innovation system, the new policy is likely to be yet another dishonoured cheque.

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New EU regulation on clinical trials: the impact on ethics and safeguards for participants

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Abstract

The European Commission has proposed a new regulation to replace the current clinical trials directive. The proposed regulation aims at accelerating the application procedure and simplifying and harmonising the administrative requirements for multi-centre trials across the European Union.

One striking feature of the proposed regulation is a two-tiered assessment, one at the central level, to be carried out by a reference member state, binding on all concerned member states; and one at the national level, where the ethics aspects will be assessed. Second, the proposal no longer requires the approval of the clinical trial application by a separate ethics committee. Third, it introduces the concept of "low intervention" trials that will undergo a "light" approval procedure.

The proposed regulation may stimulate clinical trials that yield substantial public health benefits. However, it is a step back in terms of protection of the rights and safety of trial participants. It undermines current frameworks for ethical review by not requiring the involvement of an ethics committee, and by insufficiently integrating the Declaration of Helsinki into assessment procedures at the national and European levels. The introduction of the risk-based approach needs more preparation as there is no consensus yet on key issues, such as how to define risk, and who is going to define it.

Introduction

Background of the new regulation

On July 17, 2012, the European Commission published a proposal for a regulation (1) on clinical trials repealing the existing directive on clinical trials- 2001/20/EC- (hereafter

referred to as the directive). This directive has been severely criticised for contributing to a significant drop in the number of clinical trials conducted in Europe due to the administrative burden and corresponding delays and costs. The proposed regulation aims at accelerating the application procedure and simplifying and harmonising administrative requirements, especially for multi-centre trials across the European Union (EU).

The proposed regulation explained in short

The current directive requires the submission of separate application dossiers for each of the countries involved in a multicentre trial. The Commission now proposes the submission of one harmonised application dossier to a single portal managed by the European Commission. The assessment of the application will be split into two parts while making "a clear distinction between aspects where member states cooperate in the assessment and aspects of an intrinsic ethical or national/local nature where the assessment is made by each member state individually" (1:4). One reporting member state, selected by the sponsor, will lead the central assessment (part I) and each involved member state will assess the national/ethical aspects individually (part II). For both parts, very short timelines have been set. The assessment by the reporting member state will be binding on all concerned member states, and only in certain pre-defined cases has a state the right to "opt out" (1:33), and not allow the trial in its country. No option has been created for the concerned member states to influence the decision of the central assessment. Failure to meet the deadlines will be understood as tacit approval.

The proposed regulation chooses "not to interfere" with the member state's internal organization of the bodies involved