



## **Innovation and Inequality:** *New Indicators from Pharma and Beyond*

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Post-workshop report compiled by Professor Luigi Orsenigo

A workshop organised by DIME, FINNOV and IKD at the Sant'Anna School of Advanced Studies in Pisa, Italy gathered innovation and industrial economists, economic historians, sociologists and political scientists from all continents to discuss about the way that innovation and inequality co-evolve, with specific emphasis on the bio-pharmaceutical industry and healthcare.

Despite the different backgrounds and orientations, the participants shared a view that the current status and the foreseeable evolution of the system that discovers and deliver drugs, treatment and health are deeply flawed.

First, the productivity of R&D is falling, despite the enormous scientific progresses that have been achieved and are expected to occur in the future, mainly as a consequence of public support to research. Second, strong disparities exist in both health and access to health across and within countries, especially but not exclusively in the South of the world. Third, new drugs are directed to treat mainly diseases prevalent in the richest countries and much less toward the diseases typical of poorer countries. Fourth, in any case, in many poor countries people do not have sufficient access to basic, essential drugs, let alone to new, innovative drugs.

These issues are tremendously complex. The workshop has just begun to scratch the surface, highlighting some critical points and raising problems, rather than providing clear-cut answers and shared conclusions. Yet, a few crucial problems were recognised as particularly urgent.

First, the trends towards an increasingly tight IPR regime within countries and at the global level through the implementation of the TRIPs agreements are likely to have serious negative consequences. It is not obvious that strong patents have a direct positive effect on innovation, while they certainly contribute to distort the directions of technological progress towards patentable drugs and increase prices, sometimes dramatically. Moreover, strong patents on the results of publicly funded, basic research may have a detrimental effect on innovation. The negative effects of this IPR regime is particularly harming developing countries, blocking the growth of domestic generic industries, which - as in the case of India - have acted as the pharmacy of the poorer countries. The diffusion of generics finds further obstacles in the commercial practices of large pharmaceutical companies, in legislation (e.g. through data exclusivity) and in the trends towards the consolidation of this segment of the industry towards a tight oligopoly, significantly participated by the large American and European corporations. Thus, it is necessary to take actions in order to sustain and keep open the market for generics worldwide.



Second, a tighter IPR regime is not the only cause in inequality in access to drugs and to healthcare. Most of the essential drugs are off-patent but still poorer people face overwhelming difficulties in getting drugs and treatment, especially in developing countries. This situation has most likely even been worsened by trends in the structure and organisation of health systems and markets. Health-related expenditures are skyrocketing in most developed countries and also in some poorer nations. Yet, in many countries - and especially in the developing ones - an increasing reliance on the private provision of healthcare and on out-of-pocket expenditures is observed and the ability of healthcare systems to supply and deliver their products and services in many instances has declined, sometimes dramatically. Access via predominant out-of-pocket payment systems drives people further into poverty. Conversely, access free at the point of use improves equity and reduces inequality by moving health systems towards response to need rather than response to individual demand. Uncontrolled commercialisation has created a situation in many low income countries where medicines – often substandard – are chiefly sold piecemeal as commodity items to ill-informed buyers. Improvements require a move towards equality not so much of ‘access to medicines’ as of ‘access to appropriate treatment’, through the filtering of medicines access by a system of professional advice and control, while removing the cash barrier.

Third, the very viability of the business model which has characterised the pharmaceutical industry for more than half a century and also the efficiency and sustainability of the structure that has governed the biotechnology segment of the sector are now increasingly questioned. Although profitability remains high, the productivity of R&D is declining, despite direct and indirect public support to basic research and clinical trials and tremendous scientific advances. Against this background, doubts are increasingly raised that the financing of R&D - particularly through venture capital and the stock market and extremely favourable IPR regime- may induce corporate strategies and bubbles which may contribute to rising inequality. According to some interpretations, for example, in the US biotechnology industry, the use of stock-based compensation might have resulted in not only an inequitable distribution of income but also reduced investment in innovation and unstable economic performance.

Against this background, progresses have been achieved. Programmes like the Orphan Drugs Act in the USA and now in Europe have at the same time contributed to channel research towards rare diseases and to provide new, highly significant markets for companies, especially for some of the smaller ones and for the biotechnology industry. At the same time, philanthropic initiatives have multiplied. Public and private aid has been growing rapidly and some institutions like the Gates Foundation are now major players in the field, both from a financial and an organisational perspective. Similarly, hybrid institutions like PPPs (Public-Private partnerships) and PDPs (Product Development Partnerships) are taking a key role at the global level. Meanwhile, a number of middle income and low income countries have been quietly upgrading their own productive capabilities in pharmaceutical production: innovating in terms of their local industrial capabilities rather than in innovative product terms. And they have been doing this by integrating health policy tools – such as local procurement – with industrial policies such as facilitating joint ventures. While it is not obvious at all that all countries should develop



their own domestic industries, these initiatives can have an important impact on access to medicines.

These changes constitute certainly encouraging steps forward, but the record is mixed and considerable controversies still surround these developments. The current, heated debates on these issues are too often fragmented into sectional interests and disciplinary orientations, which tend to hinder progress rather than favouring it. Clearly, much remains to be done and debates need to be informed by new perspectives and approaches.

At the workshop a few basic, but key issues and methodological commitments were discussed. First it was noted that in the current debates questions are typically framed in terms of health and economic policy, with the two sides sometimes not easily communicating with each other. In the world of public health problems are expressed in terms of the efficacy and speed with which old and new drugs and treatments become available. In economic terms, the problem is framed essentially in terms of the conventional toolkits of economists, i.e. incentives, market failures and sometimes collective choice.

These two perspectives badly need to be more thoroughly integrated. First, behaviour is not driven simply by incentives, but - at least equally important - by capabilities and competences. Thus, a greater attention must be given to the analysis of the processes through which such capabilities are acquired and developed - at the individual and above all at the collective and organisational level - and to how they are shaped and contribute to shape incentives.

Second, markets do not automatically emerge when incentives are provided. And when they do emerge, there is no guarantee that they will work efficiently: quite the opposite. The construction of markets rests instead on capabilities, on organisations, on institutions and history, on social and political relationships.

Third, the language of market failures and public goods might sometimes be too restrictive for addressing the issues at stake. For example, in many instances lack of access to drugs is largely a matter of lack of income, rather than a matter of insufficient incentives. Health is often - but unfortunately, not too often - perceived as a central concern for the government, not simply because it is a public good or there other market failures, but because its sheer importance for to the societal fabric and government responsibility towards its citizens. Is health simply a "public good"? Or is it a human right? If so, how do issues of (economic) efficiency interact with questions about morality, justice and fairness?

There are indeed examples and experiences where healthcare is constitutionally given the status of a basic human right and - despite stringent budget constraints - it is provided in a reasonably efficient and equitable way. Even more than this, healthcare - conceived in this fashion - might even become an important of source of economic growth and innovation.



This is a question which used to be at the heart of economics. It has been somewhat forgotten - or removed. But unequal generation and diffusion of innovation constitutes a major problem of global justice. Neither innovation theory nor the theory of global justice provides clear-cut solutions. Time is ripe to engage again in this terribly difficult - but now unavoidable - enterprise.

For further information on the Innovation & Equity project, please visit the project website: [www.innovation-equity.eu](http://www.innovation-equity.eu) or email: SocSci-IKD-events@open.ac.uk.