Catalyzing a health innovation system that works for all

Catalytic project

SALUD por DERECHO
Right to health foundation

The Problem

Biomedical research has led to the discovery and development of therapies, devices, and medicines that have substantially improved people's health. Moreover, advances in the biomedical field present unprecedented opportunities to develop the medical technologies needed to treat and cure diseases.

However, in recent years, the R&D system has shown its weaknesses and several structural flaws and limitations have been detected which are leading to a biomedical innovation system that is more costly but less productive[1]. This means that although much more scientific knowledge is generated it is rarely shared, it is underutilized and very few truly innovative products that add therapeutic value are reaching the market. According to the magazine *Prescrire*, in 2010, of the 97 new medicines or new indications for drugs known, only four provided therapeutic benefits[2]. And most importantly, the current R&D model, driven by commercial criteria and not by the health needs of individuals, compromises access to medicines, either because the medicines do not exist or because patients and the national health system cannot deal with the costs. Currently, more than 2,000 million people worldwide still lack access to essential medicines and the high cost of medicines is one of the most important factors that contribute to this violation of the right to health, both in impoverished countries and in Europe.

1 In the period between 1993 and 2004, the pharmaceutical industry reported that its expenses went from 16.000 million dollars to 40.000 million dollars, a 147% increase, while the number of NDAs annually approved by the FDA increased only 38% (US GAO).

2 Revue Prescrire 2011

A lack of technologies for poverty-related and neglected diseases

Perhaps the most visible consequence of the flaws in the current R&D system is the approach to poverty-related and neglected diseases. These diseases, which include malaria, tuberculosis, and the chagas disease, are prevalent primarily, and almost exclusively, in developing countries. The inexistence of a market in these countries, due to the low expectations of economic return for the pharmaceutical industry means that companies are not interested in researching and developing drugs and vaccines to address these health problems. From 1975 to 2000, very little was invested in R&D for these diseases, and of the 1,393 medicines developed during those years, only 16 were to treat diseases that predominantly affect people in developing countries[3]. A clear example is the treatment for tuberculosis, which has not seen significant innovations in decades, and has, up until a few years ago, been ignored as an area of research.

The high cost of medicines and the lack of innovation in Europe

Less attention has been devoted to the negative effects that the current innovation system has on those diseases that are also prevalent in developed countries (e.g. cancer, hepatitis) and therefore affect the patients and the governments of the European Union. This is changing, however. The economic crisis and the budgetary pressures which have led to austerity measures are affecting the national healthcare systems of many countries in Europe, including that of Spain. It has been shown that the prices of some medicines are too high, leading governments to take decisions to the detriment of patients, limiting their access to life-saving medical technologies.

3 Lancet (Chirac P. and Torreele E.): "Global framework on essential health R&D." Lancet 367, no. 9522, 2006, page 1560–1561.

Fundación SALUD por DERECHO / Proyecto Catalytic 2013

The current R&D model, based on the system of patents, has created incentives for some areas of research but has also led to negative effects. This approach is based on the idea that the only way to recover the investments made to cover the costs of R&D of a product and make a profit is through the patent which allows for medicines to be exploited under a monopolistic regime. Moreover, this system is viewed as the only way to incentivize research and development of pharmaceutical products. However, experience has shown that medicines patented and developed under this innovation model have elevated costs and also that other more efficient approaches to encourage the development of medicines exist. In addition, the current R&D system has led the pharmaceutical industry, rather than having incentives to generate new inventions, to try to prolong their monopoly exploitation of products by obtaining new patents of old drugs with slight modifications that do not pose a significant innovation, the so-called "me too" medicines. That is, it has been shown that the patent system is now a negative stimulus to promote innovation, just the opposite of what one might think.

Moreover, those molecules whose development is not expected to be sufficiently profitable are abandoned or are lines of research that are not initiated at all. This is the case, for example, with research for new antibiotics[4]; low expectations of commercial profit have often prompted the industry not to take interest in their development. Clearly, the system does not always encourage new innovations, and the industry's priorities are not always oriented towards health needs.

4 See, for example, "Policies and incentives for promoting innovation in antibiotic research". Elias Mossialos, Chantal M. Morel, Suzanne Edwards, Julia Berenson, Marin Gemmill-Toyama, David Brogan. Ed. European Observatory on Health Systems and Policies

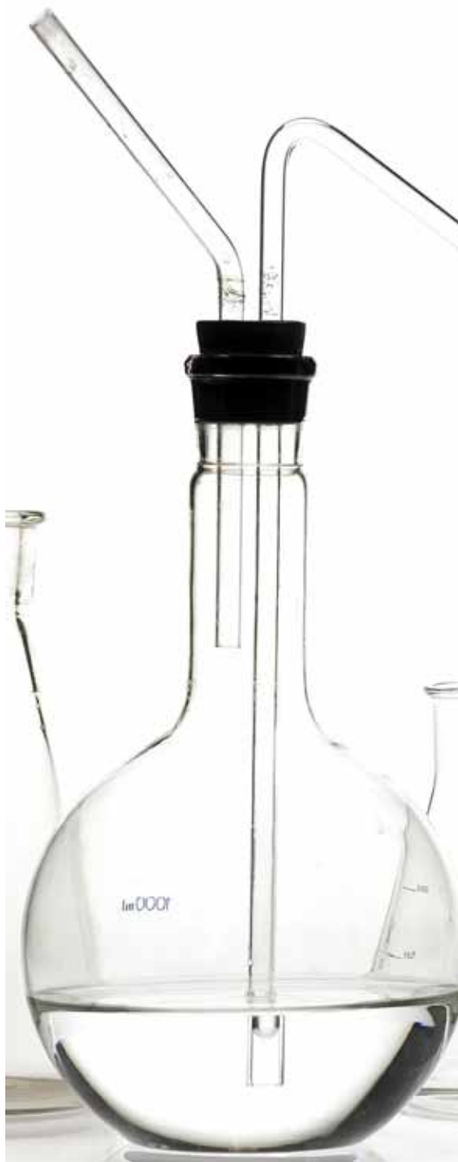
How to foster needed biomedical innovation and ensure its accessibility

These issues are being discussed by a number of actors, including stakeholders in the pharmaceutical industry, public-private health partnerships, Partnerships for the Development of Products (PDPs), and the World Health Organization, which has initiated many debates on this topic.[5] All of these actors seem to agree that the way in which biomedical R&D is carried out must be reformed or restructured entirely.

At **Salud por Derecho** (Right to Health Foundation), we believe that it is necessary to have a system of health innovation that is guided by the principle of guaranteeing the right to universal healthcare, that responds to people's health needs, and that encourages innovation within a sustainable research system.

In short, our objective is to contribute to introducing new principles and best practices to reform the current system in Spain and Europe so that by prioritizing the public interest, the interests of public institutions and the private sector can be reconciled. This will work to the advantage of the principal innovative bodies, researchers, and most importantly the principal beneficiaries and financers of the system, citizens.

5 Link to the last WHO report that spurred debate on this topic: http://www.who.int/phi/cewg_report/en/index.html



catalytic project

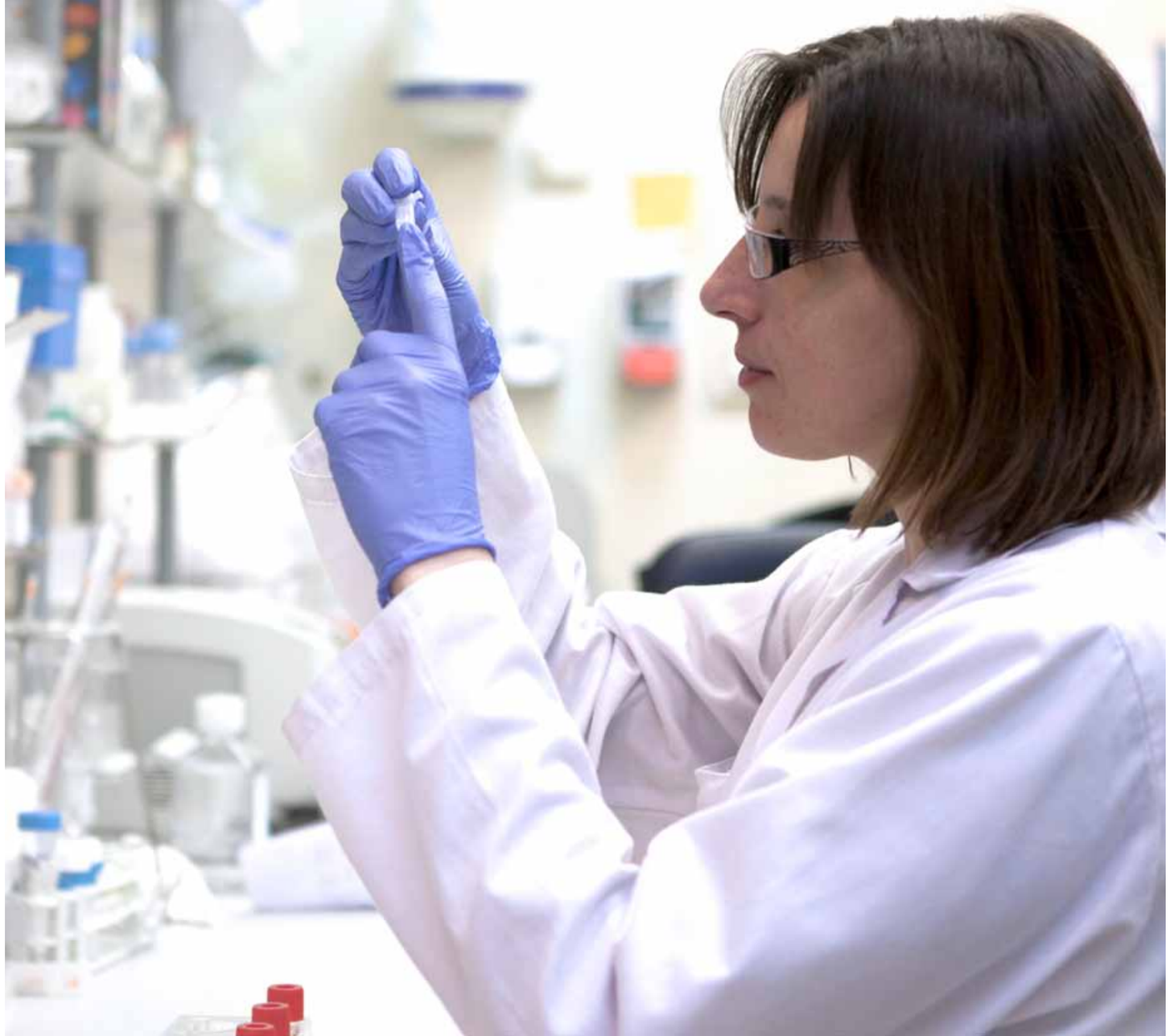
Catalytic Project

Too often, the vision of the scientific community on this topic has been sidelined. For this reason, we seek to raise the voice of scientific researchers in this strategic debate.

The objective of the **Catalytic Projec**t is to get new actors involved in the effort to direct R&D policy toward a biomedical innovation model that is oriented towards meeting people's health needs and the generation of public goods. We seek to create a large movement that can have a political impact, both nationally and internationally, and can create change in the long term.

Through **Catalytic**, we want to work with the scientific community, public and private institutions, and key policymaking figures in Spain and Europe in order to expand upon the systematic flaws of the current health innovation model and analyze the effects on the research process, the generation of knowledge, and on the daily life of researchers.

We strive to start a discussion on the subject and identify the principles, proposals, and best practices that the scientific community believes should guide biomedical R&D. Practices which include overcoming intellectual property obstacles that impede the access to results of early research phases, the pre-registration of all clinical trials, and the use of prizes to delink the cost of research from the prices of medicines, could all lead to a new stimulus in biomedical R&D.



The main activities carried out by the **Catalytic Project** are the following:

- Breakfast-debates in Madrid, Barcelona, and Brussels. We want researchers to discuss the current model of innovation so that they can give us their diagnostic and propose solutions to the detected weaknesses of the system.
- Discussion sessions with the public and private institutions around Europe who fund R&D.
- Having acquired all the necessary information, Salud por Derecho will produce a report that summarizes the views and proposals of the scientific community. We will present this report in national and European forums that deal with scientific policymaking, such as the European Union's new research framework program, **Horizon 2020**.
- This report will also include the results of a survey conducted in the sessions with experts, which will allow us to get input from the highest number of researchers possible and compare the views raised through this debate.

To facilitate dialogue and communication with the scientific community and set up a network of partners, forums for debate on social networks, as well as audiovisual tools and events.

For more information:
http://saludporderecho.org/en/right-to-health-foundation/catalytic-project/

www.saludporderecho.org

Follow us on:

facebook twitter

Globally defending the right to health

WE IMAGINE, WE DEFEND we make a change

SALUD por DERECHO

Right to health foundation

Plaza de la Marina Española 11 Bajo B - 28013 Madrid
saludporderecho@saludporderecho.org
T: +34 91 429 93 87