

THE PUBLIC INTEREST

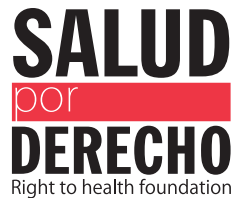
BIOMEDICAL INNOVATION

EXECUTIVE SUMMARY

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SALUD
por
DERECHO
Right to health foundation

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About Salud por Derecho

Salud por Derecho is a non-profit foundation that defends human rights so that all people, irrespective of where they live, can exercise their right to health. The organisation works to promote a global system for the social protection of health that guarantees access to quality public services for everyone and puts the focus on ensuring universal access to HIV/Aids treatment, prevention and care in order to protect the rights of the most vulnerable populations. Salud por Derecho also works on initiatives that review the current model

of medical innovation and seeks alternatives that guarantee the development of, and access to, accessible, efficient and quality medicine in Spain and abroad.

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EXECUTIVE SUMMARY

The development of new medicines, diagnostic methods and other healthcare technologies constitutes a central element in public policies, both healthcare and scientific, while at the same time curing patients and satisfying the healthcare needs of present and future generations, is the principal motivation of healthcare professionals and researchers. In this context, biomedical research involves several stakeholders that configure a value chain where each of the links proves essential (1,2) in the public and private sphere. Nevertheless, the result of this research is frequently transferred to, or remains in the hands of, the private sector, while the public sector loses its capacity to influence such crucial matters as price or management of intellectual property, despite the fact that it is the main purchaser of the resulting medicines and healthcare products. This study starts with the premise that innovation in health must be affordable, accessible, efficient and of quality, and elements such as high prices (3,4) and current mechanisms for managing biomedical intellectual property (5) cannot be a barrier that prevents us from reaching all those who need it irrespective of their socio-economic situation or their place of residence.

The public sector is not a passive actor in biomedical innovation. On the contrary, it actively

participates in many phases of development (6). The public interest in scientific and health policies is at heart of the actions carried out by the public administrations, with the aim of guaranteeing an improvement to people's quality of life, responding to their needs and improving the systems and structures that protect and guarantee the social and economic impact of these. It is true that the public role in the development is not the same for all technologies and, in certain cases, the presence of industry can also be important. But it is generally the case that the public contribution is made invisible when the private sector acquires or appropriates technologies and knowledge. This study questions to what extent is the public interest vanishes from the transaction with the private sector, and if there are mechanisms in Spain that allow for certain conditions that can protect it. The study focuses primarily on two areas: public funding of biomedical R&D in Spain and the transfer of knowledge from the public to the private space.

To start, the first stumbling block is found in the very definition of the public interest, a term that can be interpreted in many ways. In this case, it starts with the premise that the public interest must respond to essential elements such as: the health needs of the population, financial

and procedural transparency; adequate and accessible accountability and management of knowledge and of intellectual property organised with the general interest in mind. Furthermore, the publication of the results of projects financed with public money must be accessible and complete, including the negative results. These are some of the elements that this study identifies as central and aims to ascertain how they function in Spain.

Over recent decades, the biomedical R&D activity in Spain has been incorporated into the overarching framework of standards that regulate scientific research in Spain and which are subject, to a great extent, to the changes that have occurred in the European and international sectors and the need to align with these (7–9). Public policies in relation to biomedical R&D have also been adjusted in an explicit way, in relation to the private sector for the purposes of fostering the recovery, protection and transfer of the results of the research to society (7). In Spain, public universities and research bodies have the Office for the Transfer of Research Results (OTRI) (10), management offices whose function is to commercialise and facilitate the application of the research results. They are therefore a key element in implementing public interest criteria and play an important role in the transfer of knowledge to the corporate sector. With certain exceptions, this study finds that, at present no objectives or principles of a social nature or relating to the public interest govern these processes in general.

HOW MUCH FUNDING GOES TO BIOMEDICAL R&D IN SPAIN AND WHERE DOES IT GO

To complete this study, the biomedical R&D funding data has been analysed for the period between 2008 and 2017 (depending on the source), for the Organisation for Economic Co-operation and Development (OECD), the Spanish National Statistics Institute (INE), the Health Institute Carlos III (ISCIII), the Ministries with competencies in Science and Innovation, the Centre for Technological and Industrial Development (CDTI), the European Commission (EC), Farmaindustrial and the Spanish Biotechnology Companies Association (ASEBIO). The analysis shows two clear phases: on the one hand, investment growth, coinciding with economic expansion over the past decade and the creation, in 2008, of the Ministry of Science and Innovation and, on the other hand, a fall off from the years 2009–2010, driven by the financial crisis and the recession and the ensuing budgetary and credit restrictions. According to the OECD, total spending on health R&D in Spain fell 8.5% between 2010 - the year with the highest spend - and 2014, going from a sum of 2,759.37 million euros to 2,524.75 million euros. All in all, this reduction in health was less than that experienced in R&D in Spain overall, which was 12.1%. The lion's share of R&D spending on health in Spain is executed in the public sector, primarily in research centres that are dependent on the administration and public universities. In terms of the reduction in spending, this was more evident in the public administration - especially in public research bodies - than in the universities. In figures

expenditures in health R&D in Spain is higher in the public sector (62%) and non-profit than in the private sector (38%).

In terms of public R&D funding in Spain, this is assumed primarily at state level, by what is now the Ministry of Health, Consumer Affairs and Social Welfare and the Ministry of Innovation, Science and Universities, within the framework of the Strategic Action on Health (AES) and the Spanish Science, Technology and Innovation Strategy (EECTI) respectively and in the Autonomous Communities. In the case of the latter, regional biomedical research policies and programs have played a key role in recent years having suffered enormous cuts both in the maintenance of funding of biomedical and health research and in the competitiveness and national and international positioning of certain Autonomous Communities which have developed regional strategies (11–13) and systems for biomedical research and innovation. According to the INE, autonomous and local administrations accounted for 61% of the total spend on R&D in medical sciences in 2016. As a result of this, the number of research projects financed in Spain has fallen, leading to the suspension of many lines of research, and leading to more temporary and more precarious employment for personnel dedicated to R&D in the medical sciences.

For its part, the industry has shown more interest in consolidating collaboration with other companies than in funding the research carried out at universities and public research centres; corporate funding in the public sector remains below 10% and the

spend on direct purchase of knowledge is below 0.5% of total external spend on R&D. The pharmaceutical sector is the main beneficiary of the assistance provided in the ambit of health and biotechnology by the CDTI, while it is surprising that the majority are multinationals or consolidated companies with strong sales volumes. The companies are also the main beneficiaries of increased Spanish participation in European health research projects. The areas of greatest interest in competitive concurrence programmes are almost invariably cancer and neurological and mental disorders.

Definitively, in this period the contributions of the Autonomous Communities and funding from European programmes such as Horizon 2020 have been key to maintaining much of the biomedical innovation developed in Spain. Nevertheless, new contributions to the biomedical innovation budget should not replace the State Administration's responsibility to guarantee investment in innovation, strengthening the commitment to science policy and improving the employment conditions of research personnel. With respect to the industry, the data reveal its role as a participant in funding innovation and also as a recipient of public funds in Spain. This public-private collaboration, complementary and necessary, should include elements that safeguard the public interest in the activities financed and/or subsidised, measuring not only the economic impact of innovation but also the social impact, in order to meet the principal objectives of many of these programmes.



FROM PUBLIC TO PRIVATE: THE TRANSFER OF KNOWLEDGE AND PUBLIC INTEREST IN SPAIN

With regard to the transfer of biomedical knowledge, this study has, with its limitations, attempted to define the reality of our universities and research centres. To do so, the state of the art (14–21) and the sources of information currently available were reviewed, with the questions asked directly through a survey on policies and common practices of knowledge transfer in Spain.

Firstly, the results show that the indicators commonly used in transfer do not allow for the valuation of the public interest and the social impact of research and innovation. Nor does there exist, therefore, public information in relation to development or diagnostic methods based on knowledge generated in

universities and research centres that have been transferred, one way or another, to companies, or if they have benefitted from public funding. Indicators of success or activity commonly used, such as the number of patents (22), do not show us whether a particular investigation has produced a product or health technology that covers an identified and prioritised healthcare need.

Secondly, there is no complete and accessible database of the technology or biomedical research results that have been generated based on the scientific activity financed with public funds nor the results of knowledge transfer activity developed by universities and research centres. The information found is fragmented and frequently incomplete, making it impossible to track funding and avail of traceability of research projects and the results obtained.

The study of some leading research entities in Spain demonstrates the innovative potential of our universities and research centres. Their transfer activity is significant enough to warrant greater attention in regional and state policies and with that the identification of elements that better protect the public interest in these processes. Proof of that lies in the success of the many Spanish spin-off companies, created based on the personnel and the knowledge of the research bodies and capable of attracting the interest of the investors and capturing significant volumes of private funding. They are, without doubt, a major strength of the current system of biomedical innovation which should improve - for example for the purpose of preventing conflicts of Interest and increasing the visibility of, and return on, public investment if there is a real desire to protect the public interest. The study also identifies best practices in R&D in Spain in the public space such as the case of CAR-T therapies developed at the Hospital Clinic Barcelona.

Finally, the study identifies and presents different initiatives and experiences that attempt to incorporate public interest criteria from the perspective of social responsibility (23,24), transparency(25) and accountability, both in the funding of research (26) and in the management and transfer of the results thereof (27–29). These allow for the deficiencies of our current system of research and biomedical innovation to be put into perspective and may serve as a reference for the development of pioneering initiatives in Spain in this area.

PROPOSALS

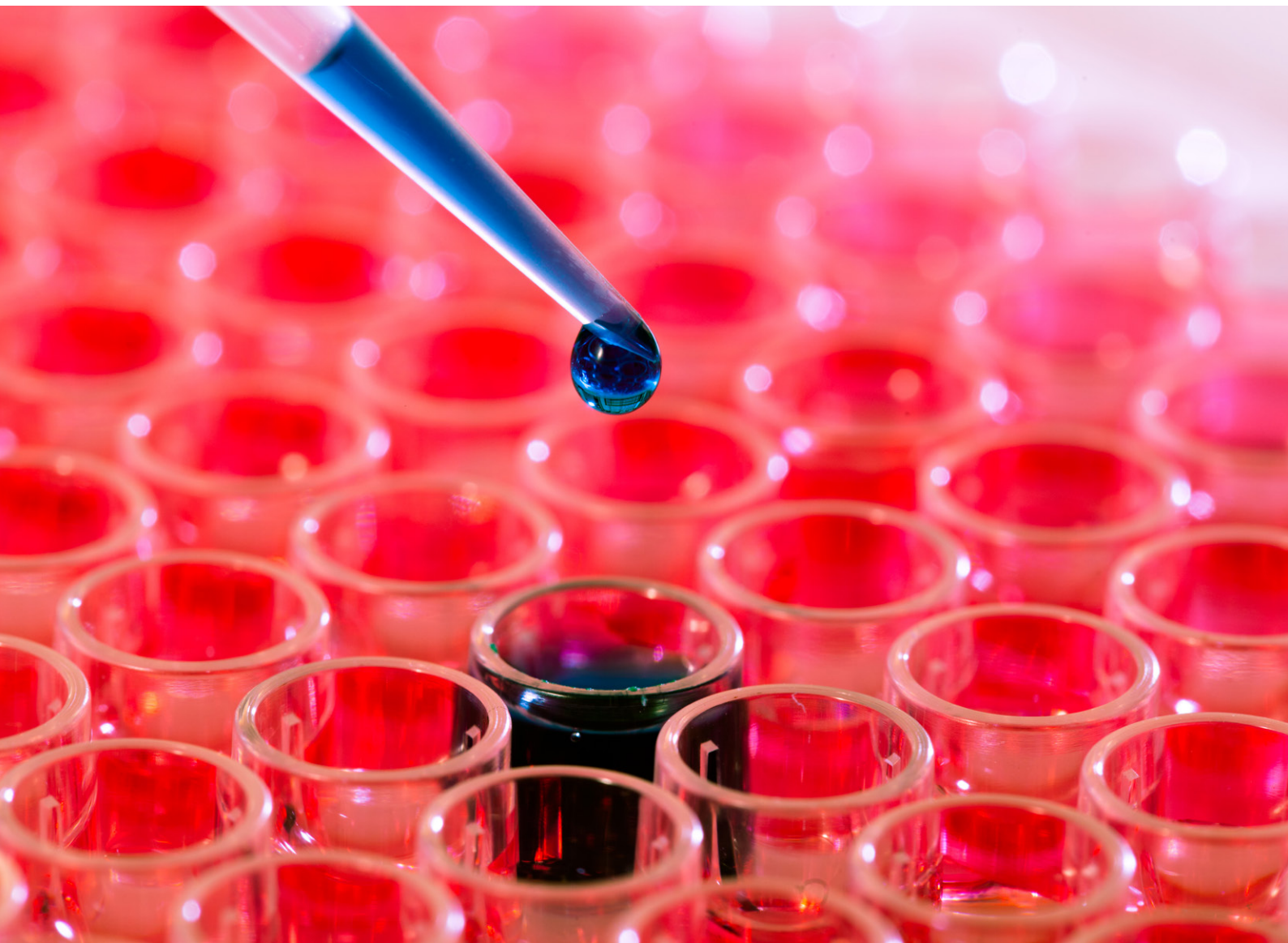
Firstly, this study proposes agreeing a definition of the public interest in biomedical research that allows for the State's contributions to be made visible: the social return on these contributions, their traceability and elements that allow us to apply the concept in public policy terms. There is therefore an urgent need to strengthen current evaluation systems in such a manner that results allow us to reformulate public policies that safeguard the public interest. To do so it is important to review systems that measure the real impact and social effects, as well as the circumstances within the economic scope of the industry. This requires the diagnosis and review of the current regulatory framework, as well as the indicators, guidelines and recommendations that allow for the identification of public interest criteria in the funding of research and the transfer of knowledge, adapted to the circumstances and Spanish legislation.

On the other hand, the protection of the public interest must be a cross-cutting element of national and regional science policies. It is necessary to implement specific measures that foster the principles of transparency and accountability and alternative methods for intellectual property and transfer of knowledge, among others. There are experiences in other countries that respond to this proposal and can serve as a reference. It would involve the provision of public and complete information on what is funded, how it is funded, what results are obtained, what results are patented, who it is transferred to and/or

licenses it and the clinical trials on which the results or patents are based, among others. Moreover, where there is public investment in any form (through subsidies, participation of universities and public research bodies, participation of public health centres in clinical trials or tax incentives, etc.) criteria must be established to ensure transparency and better governance and access to, and affordability of, the final products and technologies.

Finally, the study reveals the limited scope afforded to the public interest in the ambit of knowledge production and transfer. Universities and research centres are key players in this process and it is of fundamental

importance to begin to work these elements from these spaces, also involving the same research personnel. It is also important to foster policies and initiatives that allow for the transparent management of conflicts of interest in biomedical innovation. Said conflicts can occur from the outset and in all phases of public-private partnership in the innovation chain, which is why it is so important to develop agreed guidelines and recommendations that allow us to better define these relationships.



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