AAJM
Asociación Acceso Justo al Medicamento

WE NEED A MORE EFFICIENT AND FAIR WAY OF FINANCING BIOMEDICAL R&D

[Notes prepared for the Meeting on Open medical science for better health-care for all, organized by Commons Network and Universities Allied for Essential Medicines. Brussels, November 29]

How can we obtain better returns for people from public investment in biomedical R&D? I think it is worth reviewing the numbers to see the dimension of the problem and why it is so difficult to change the situation.

1.How much money do we pay in Europe to finance research in biomedicine?

We, the citizens, pay through two main routes:

1st- public "direct" investment through local, national and European public budgets (financed by taxes collected by Governments); and

2nd- public "indirect" investment through pharmaceutical companies (which is financed with overprices of medicines collected by the industry from patients and health systems, thanks to the monopolies granted by patents and other exclusivities; it is a kind of indirect tax established by governments to finance R & D). That is to say this R & D budget is spent by companies, but we, patients and health systems, pay for it. And, in fact, we pay much more.

Let's see, first of all, how much money we pay to the industry through the overprice protected by patents and other exclusivities, with the purpose of financing R & D (Figure 1).

Figure 1. How much do we pay for R&D "indirectly" through overprices?

Compared expenditure and savings if medicines were paid for at generic prices and research were paid directly. UE-28. (billion euros)

	Current pharmaceutical model (with patents)	Alternative model (without patents)
Sales at ExFP, paid by patients and Health Serv.	170.6 *	
Total sales if all medicines were paid at generic prices	70.7	70.7
R&D expenditure	26.9 *	26.9
Excesive profit for companies	73.0	
Posible savings for patients and taxpayers		**73.0**

"overprices" 99.9

Negotiation margin

* EFPIA, The pharmacetutical industry in figures, key data 2018. EU-28

We calculate it from the total volume of sales at ex-factory price. In 2016, according to data from EFPIA 2018, we paid €170.6 billion in the 28 EU countries.

How much have the companies raised through overprices? We calculate how much we would have paid at the generic medicines' price, without monopoly. It amounts to €70.7 billion.

The difference between what we have actually paid and what we would have paid without monopolies amounts €99.9 billion. These are the "indirect taxes" we have paid to companies to finance R & D.

But the industry has only spent a total of €26.9 billion on R & D in the EU-28 (EFPIA data).

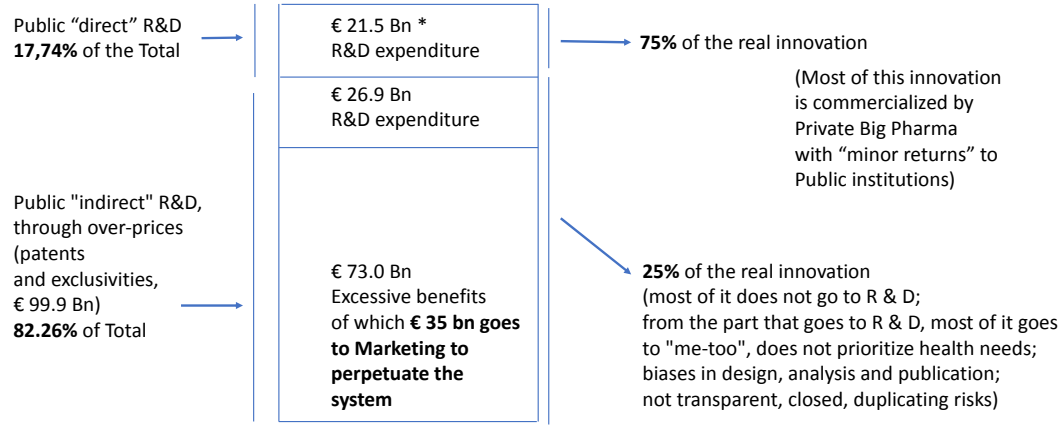
The rest, €73 billion has gone to excessive pharma profits. These are unfair profits. And, as we shall see, these profits, these enormous economic power has perverse effects for health systems and for R&D, making it almost imposible to change the situation.

On the other hand, for "direct" public funding of research, with data estimated by the European Science Foundation, we allocate €21.5 billion annually in the EU-28 (Figure 2).

2. Is this system effective and efficient for the whole of society?

As we can see, adding what we annualy pay for biomedical research directly (€21,5 Bn) and indirectly (€99,9 Bn), we are paying €121,4 Bn.

Figure 2.
IS THIS SYSTEM EFFECTIVE AND EFFICIENT FOR THE WHOLE SOCIETY?
(but it is very efficient for Big Pharma)



Biomedical R&D total expenditure, EU-28: € 121.4 Bn

* Estimates for 2016, based on Bouillon R et al, Lancet 2015; EFPIA 2018. Billion euros. Horizon 2020 (biomedical): € 1 Bn annualy

Thus, 17.7% of the total of what we pay is direct public investment, and 82.3% is indirect public investment.

According to Mariana Mazzucato's estimates, using US data, "roughly 75% of so-called new molecular entities with priority rating (the most innovative drugs) trace their existence to NIH funding, while companies spend more on "me too" drugs (slight variations of existing ones)."

Applying these percentages to EU, we can see that research carried out with indirect public funding (patents and monopolies) would only obtain 25% of the innovation, although it consumes more than 80% of the resources.

This huge inefficiency is due, on one hand, to the fact that the industry derives most of the money we are paying for research for other purposes, mainly profits, marketing, shares' buyback, etc.

And, on the other hand, considering the part that they really spend on R & D, about €26.9 billion, the research priorities are set by commercial interests: it means that most results are me-too, without real innovation; besides there are huge biases in designing projects, analysing results and deciding what should be published; finally

there is no transparency, results are delayed, and the risks for patients are increased by repetition of clinical trials and tests, etc.

In addition, as we pointed out before, this model has other perverse effects: companies allocate an important part of the unfair benefits, some €35 billion per year, for marketing and lobbying actions oriented to perpetuate the system, influencing the European Commission, national governments, professional and patient associations, etc.

This excess of profit due to abusive prices is also intended in part to sponsor the continuing education of health professionals, clinical guidelines, invited speeches, conferences, and scientific journals, orienting the professional behavior according to the interests of the industry and its shareholders. This marketing pressure translates into an inadequate prescription, with more than 30% of unnecessary prescriptions, which have important adverse effects on health and imply huge expenses for patients and health systems.

Some of this money is also used to influence research financed directly with public budgets, such as Horizon 2020, IMI, and other national or university institutes. Big Pharma takes advantage of results from universities and finishes the development of the drug, commercializing it at abusive prices and obtaining huge profits.

Under the pressure of Big Pharma, the philosophy of patenting and for profit research has also become a goal for some universities, public research institutes and public administrations. The industry invests part of the money that we pay through the overprice buying licences. The University is happy because it recovers the investment in developing a certain project and obtains a profit. But in most cases it does not condition the use of this license and do not include public interest criteria (for example, requiring that the resulting medicines have a fair price, etc.).

The role of Horizon 2020 is very important, because it is a multinational fund that could be the embryo of a change of the model to finance and manage R&D, if criteria of public interest would be embedded in their design and management.

3. Who benefits from this financing model of biomedical R & D? Why is it so difficult to change?

It benefits the large pharmaceutical industry and its main institutional shareholders, which are large investment funds.

Figure 3. Comparison of Expenses and Profits of Large Pharmaceutical Companies and Large Companies from Other Sectors. (US and Europe), in percentage of sales. Year 2017

Different expenditure items in relation to total sales	10 largest companies in the US and Europe by sales volume	10 largest pharmaceutical companies in the US and Europe by sales volume
Total sales	100	100
Production costs	80,39	28,88
Gross profit	19,61	71,12
R&D costs		16,61
Production costs including R&D	80,39	45,49
Gross profit discounting R&D expenses	19,61	54,51
Marketing & Administration costs	7,35	21,8
Other expenses	4,49	9,13
Net profit before taxes	**7,72**	**23,56**
Real profit if we match Pharma Marketing expenses and Other expenses to the big 10 companies from other sectors	**7,72**	**42,65**

Source: Pharmaceutical Companies: Johnson & Johnson, Pfizer, Novartis, Roche, Sanofi, Merck, Bayer, AbbVie, Gilead, GSK. Companies from the rest of the sectors: Walmart, Royal Dutch Shell, Volkswagen, BP, Exxon Mobil, Berkshire Hathaway, Apple, McKesson, Glencore, United Health.
Data taken from the annual reports, financial statement, corresponding to the year 2017.

Since the use of patents for medicines and other exclusivity instruments became widespread from 1995, with the TRIPS agreement, the profits of pharmaceutical companies doubled and continue to grow. With data from the 2017 annual reports, the profits in relation to sales of the 10 largest pharma companies are three times greater than those of the 10 largest companies in other sectors, including commercial, oil, technological or automobil companies: 23.5% compared to 7.7%. But if we add as real benefits the excessive amount allocated to marketing, share buybacks, or bonuses of top executives, the profits in relation to sales of pharmaceutical companies are, in fact, 5.5 times higher than the largest companies of other sectors (Figure 3).

4. Can the model be changed? Yes, it can.

Firstly, regarding direct public financing of R & D, criteria of public interest must be included. Thus, different civil society organizations, including UAEM and Commons Network, have prepared the document "Public return on public investment, ensuring sustainable societal impact of EU-funded biomedical research & innovation", in which they propose that Horizon Europe incorporates a series of important Access principles: Needs-driven; equitable; effective; accesible, available, affordable; efficient; public-interest driven ownership of results; and transparency.

These criteria, refered to EU funds, could be applied to all direct public investment in research in the EU Member States, which, as we saw, reach more than €20 billion.

Secondly,

We can increase initiatives creating alternatives to the current R&D financing model. See UAEM Re: Route, map where they analyze 81 alternative initiatives. See the excellent Commons Network document by Sophie Bloemen and David Hammerstein, From Lab to Commons, with a series of examples of transition policies towards a new model. See also the document "The People's Prescription" by Mazzucato and collaborators, with very interesting proposals.

I underline 4 measures for a progressive delinkage:

1. Recover part of the "indirect" public expenditure on R & D (over-prices), with a discount on sales of 10%
(equivalent to €17 billion in the EU-28)
2. Create a European Biomedical Research Fund with public control, setting priorities according to health needs, and guaranteing open and cooperative research (For example, Cancer Innovation Fund, AMR Innovation Fund, etc.)
3. Bring R & D with direct public financing until the commercialization phase. And
4. Commercialize at manufacturing cost price (through generic companies, product development partnerships, public institutions and public firms, etc.).

Finally,

In my opinion, the definitive solution to achieve access to the necessary medicines, including appropriate and efficient research, will not come until the medicines are excluded of the patent legislation. We need an international agreement for fair access to medicines. As suggested by Stiglitz and other signatories of the letter "Make medicines for People, Not for Profit", it is urgent to ask WHO member states to negotiate a global research and development agreement to ensure innovation and access to affordable vaccines, medicines and life-saving technologies for all.

The money that is now spent on abusive prices of medicines would be allocated to direct public funding of R & D. It means, delinking financing of R & D from the price of medicines.

Meanwhile, the EU Parliament and Member States should know these numbers, and should start to change the model, reducindg and eliminating exclusivities (For example modifying exclusivity legislagion in order to alow countries to use compulsory licences; reducing or eliminating Suplementary protection certificates, etc.).

Through these different initiatives and measures we can promote open medical science for better health-care for all. Making FP9 work for the public interest.

5. We must change.

The current model is unfair and inefficient for society. It supposes a barrier for access to necessary medicines, an excess of prescription of unnecessary medicines, and a tremendous drain of public resources of health systems. It is a battle for the survival of public health systems. But it is also a battle for the dignity of people.

Let me recall a historical example: the struggle to reduce the price of HIV / AIDS treatments in South Africa. In that moment they managed to add three elements: first, leadership and political will, second, social support and mobilization, and third, good strategy and good coordination. The result was to facilitate access to treatment for millions of people. It can be done.

Another usefull exaple is the Tobacco convention, and national tobacco laws and strategies.

In the coming months we have an important challenge: I would like to draw your attention to the European Parliament elections, to be held in May of next year. The European Parliament can and must build the leadership and political will of the EU.

In this regard, the European Alliance for Responsible R & D and Affordable Medicines has issued a Manifesto: Putting People's Health First: Improving Access to Medicines in Europe. The Manifesto proposes four áreas that should be prioritized in the agenda of the new European Parliament and the new Commissioin: Public return on public investment; Real innovation and Patient Safety; Ensuring fair competition by preventing and sanctioning anti-competitive behaviours; New R&D models based on open science principles, such as the delinkage of the incentive to develop medicines from the expectation of high prices (EUAlliance, 2018).

It is a good opportunity to sensitize the candidates and future parliamentarians, help them to know the problem and generate social pressure.

We are facing a massive inefficiency (about 73 billion euros a year), which contributes to a massive healthcare related avoidable mortality: Here in the EU, more than 33,000 people die every year only by lack of effective antibiotics; more than 100,000 people die by adverse effects of medications due to inadequate prescription; thousands die waiting for diagnosis and treatment (including essential medicines) due to lack of professionals and means, and also due to high copayments; and meanwhile billions are derived to pay for the excesive price of medicines. And if we look at the whole world, more than 10 million people are dying every year because they don’t have access to the medicines they need.

We can change this situation. And we must change it. Drop by drop. Step by Step.

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