Drug research: public funding, private profits

- **Pharmaceutical companies often cite the high cost of research and development (R&D) to justify the astronomical prices they charge for new drugs. Drug companies do not, however, fund R&D costs alone.**

- **One-quarter of new pharmaceutical substances authorised in the United States had their origins in public-sector research. Publicly funded basic research also plays a crucial role in new-drug discovery in Europe.**

- **Tens of billions of euros of public money are invested in the R&D of new drugs. Pharmaceutical companies also benefit from billions in tax breaks; one example is France's research tax credit.**

- **However, governments and citizens receive little in return for their generosity, judging by the increasing sums health systems devote to buying or reimbursing outrageously expensive drugs.**

- **There is no shortage of examples of exorbitantly priced drugs discovered with the help of public funds: *pembrolizumab* (Keytruda°) in the Netherlands, *tenofovir* (Viread° and other brands) in Belgium, *adalimumab* (Humira° and other brands) in the UK, and *onasemnogene abeparvovec-xioi* (Zolgensma°) in France.**

- **In many countries, people are starting to speak out against the fact that the public pays twice for drugs: first, by funding their R&D and a second time, by paying top dollar to buy or reimburse medicines through national health insurance systems.**

The exorbitant cost of new drugs is a huge burden on health expenditure in all countries, even the world's wealthiest nations. Pharmaceutical companies often cite the large sums they spend on the research and development (R&D) of new drugs to justify the exorbitant prices they charge. But are these prices still justified when the research is funded in part by the public purse, and when pharmaceutical companies receive many forms of state aid? Several studies and reports provide information on the direct and indirect financial support pharmaceutical companies receive from the public purse (**a**)(1-3).

Publicly funded research and development of new drugs

In 2016, the top 20 pharmaceutical companies generated about US$500 billion in global drug sales. Their R&D spending reportedly reached $100 billion, less than their $120 billion in profits (4). But drug companies are far from being alone in funding the research.

The crucial role of public money in basic research in the US. Several studies have quantified the public sector's contribution to the R&D of new drugs. According to a 2018 study, all 210 drugs approved by the US Food and Drug Administration (FDA) between 2010 and 2016 received public funding, 90% of it at the basic research stage (5,6).

Another study looked at FDA drug approvals between 1998 and 2007 (2,7). Among the 252 products approved that contained a new drug substance, 24% had been discovered by scientists from a university, or a research institution funded by a non-profit organisation (2,7). In two-thirds of cases, the licence was first transferred to a biotechnology company and in one-third of cases to a pharmaceutical company (2,7). The FDA granted priority review status to 60% of the drugs that originated in a public research institute which, according to the authors, shows that the public sector was more likely to discover drugs considered to offer substantial clinical and therapeutic benefits over existing drugs (2,7).

Another study continued this work by investigating the drugs approved by the FDA between 2008 and 2017 that contained one or more new drug substances (8). One-quarter of the 248 drugs approved had received public-sector financial support, with 19% originating from public-sector research and 6% from companies spun off from a publicly supported research programme. Among these drugs, 68% received expedited approval versus 47% of the other drugs, and 45% were the first in their pharmacotherapeutic class versus 26% of the others, both indicators of greater therapeutic potential (8).

In Europe too. In a study of the 94 medicinal products that contained a new drug substance and were authorised by the European Medicines Agency (EMA) between 2010 and 2012, 17% had originated in public-sector research or a public/private partnership (2).

Another study showed that in the UK, between 2000 and 2012, the British government and charities funded about 40% of all pharmaceutical R&D expenditure (3). And in the field of cancer research, their contribution exceeded that of the private sector in 22 of the 30 years between 1982 and 2012 (3).

According to this study, British public research institutions played a decisive role in the discovery of drugs such as *abiraterone, alemtuzumab, adalimumab* and *infliximab* (3).

Six of the ten drugs with the highest global sales are monoclonal antibodies. The method for generating monoclonal antibodies was developed at the publicly funded

a- *The main reports used for this article are from the UK, Belgium and the Netherlands (refs 1-3). They were chosen in particular for the accuracy and originality of the data provided. Other organisations have looked into public-sector funding for medical research. For example, a document published in January 2019 by the independent Spanish foundation Salud por Derecho has analysed the situation in Spain and called for transparency over the allocation of public funds to pharmaceutical R&D (ref 25).*

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UK Medical Research Council Laboratory of Molecular Biology in Cambridge. Its inventor, who received the Nobel prize for medicine in 1984, did not patent the technique because he disapproved of the principle (3).

Public funding for development of new drugs too. A US study analysed the 1541 drugs approved by the FDA between 1990 and 2007 and concluded that, in about 10% of cases, the public sector had also contributed to the development phase (and therefore not just to basic research). But all the intellectual property generated during this phase had been transferred to a pharmaceutical company (2).

The contribution of the public sector to drug development is also evident in the increasing proportion of "biological" drugs developed by biotechnology companies in partnership with universities. Large pharmaceutical companies compensate for their own underperforming R&D by trying to buy small or medium-sized biotechnology companies that are developing promising drugs, or by seeking greater partnership with academic research institutions. GSK, for example, invested half of its R&D budget in a programme of partnerships with academic institutions and biotechnology companies. Other pharmaceutical companies have taken premises in close proximity to academic institutions in order to form partnerships and outsource certain tasks, such as screening for molecules with therapeutic potential (2).

Billions in subsidies, little transparency

It is difficult to determine how much money governments invest in pharmaceutical R&D, due to the often piecemeal nature of the data available.

Billions awarded to businesses for R&D. In the US, about $37 billion (€32 billion) of public funds are thought to be invested each year in biomedical R&D. The UK government spent £2.3 billion (€2.6 billion) in 2015 on health R&D (2,3).

A report published in 2019 investigated public-sector funding for biomedical research in the Netherlands (2). Based on information provided by the Dutch authorities, about €837 million of public funds went directly on biomedical R&D in 2017 (2).

The independent Belgian magazine *Test Santé* estimated that Belgium spent €575 million on biomedical research in 2015, through various funds that came from public organisations and the European Commission, with an additional €59 million in subsidies granted directly to businesses for R&D (1). These figures correspond to direct spending and direct support alone.

Billions in tax breaks. In the Netherlands, the pharmaceutical industry has received a great deal of funding in the form of tax credits that enable companies to reduce the salary costs for staff engaged in R&D, a reduced tax rate on profits generated through innovative activities, capital to support the creation of biotechnology companies, and help with funding clinical trials (2). For example, pharmaceutical companies received €1.7 billion in 2017 in tax reductions on revenue arising from patents (9).

When this indirect support is added to the direct support and the sums spent on drug reimbursement, it is clear that Dutch taxpayers ultimately pay two or three times for their drugs (2).

When pharmaceutical companies in Belgium invest in research, they too receive indirect support in the form of various tax breaks that, according to *Test Santé*, amounted to €872 million in 2016 (1).

Various tax breaks in France. In France, between 2015 and 2018, the research tax credit scheme provided about €6 billion per year in tax breaks to companies, all sectors combined (10). In 2015, among manufacturing companies, the pharmaceutical, perfumery and personal care sector was the second highest beneficiary (11.2%), just behind the electrical and electronics sector (14.5%) (10). This tax credit covers 30% of research expenditure up to €100 million, and 5% above this threshold. It covers 60% of the cost to companies of outsourcing their R&D to academic research institutions (10).

Income derived from the sale or licensing of patent rights is subject to a lower tax rate: 15% up to 2018, reduced further in 2019, down to 10% (11,12). According to the French Senate's Finance Committee in 2012, the reduced rate of 15% (our translation) *"costs over €800 million a year, gives rise to multiple tax optimisation practices, and essentially benefits large pharmaceutical groups"* (11).

Exorbitant prices for drugs originating from public-sector research

Are publicly funded drugs provided at reasonable prices? Apparently not, as the following examples illustrate.

The Netherlands and pembrolizumab. The realisation by Dutch authorities in 2015 that *pembrolizumab* (Keytruda°), a drug used in lung cancer, would cost €200 million per year, and that 11% of the €1.85 billion budget allocated to drugs administered in hospitals would be spent on this one drug alone, was a real wake-up call in the Netherlands concerning the exorbitant cost of new drugs (2).

Keytruda° generated worldwide sales of $7.2 billion in 2018, 88% more than in 2017 (2). After evaluating its therapeutic value, the Dutch government added it to the list of reimbursable drugs in July 2017. The annual cost of treatment per patient in the Netherlands varies between €40 000 and €60 000. Yet research scientists from Dutch universities and public institutions actively participated in every stage of its discovery, development and clinical trials (2).

Belgium and tenofovir. Belgium's 2018 household budget survey found that each person spends an average of €150 on drugs a year (after any reimbursement). In addition, the national health insurance system spent €4.3 billion in drug reimbursements in 2017, an average of €400 per person. The cost of so-called innovative cancer drugs alone was about €600 million, four times more than in 2007 (1).

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Scientists from the University of Louvain, together with a Czech research institute, discovered three different substances including *tenofovir*. In exchange for royalties and an exclusive licence, the pharmaceutical company Gilead took over the drugs' development and market introduction. Using publicly available data, *Test Santé* estimated that Gilead reaped €72 billion in global sales with these three drugs. Meanwhile, the University of Louvain earned €559 million, less than 1%, of the sales revenue, and the Belgian national health insurance system spent €486 million in reimbursements for these same drugs (1).

The UK and adalimumab. Spending on drugs by the UK's National Health Service (NHS) increased by 29% in 5 years, rising from £13 billion in 2010-2011 to nearly £17 billion in 2015-2016 (3,13). In 2015-2016, the NHS paid out about £1 billion for the five most expensive drugs (including 4 monoclonal antibodies), including over £416 million for *adalimumab* alone, despite its origins in British public-sector research (3). In 2018, *adalimumab* cost the NHS nearly £500 million (13). Expenditure on drugs for hospital use increased by nearly 11% between 2017 and 2018, reaching £9.2 billion and representing half of the NHS drugs bill (13).

Onasemnogene abeparvovec-xioi, the world's most expensive drug as of 2020, based on French research and generosity. In May 2019, the FDA approved the gene therapy product *onasemnogene abeparvovec-xioi* (Zolgensma°) for the treatment of children under 2 years of age with the most severe form of spinal muscular atrophy (14). Based on public-sector research at the French National Centre for Scientific Research (CNRS), *Généthon*, a research laboratory financed by France's *Téléthon* (an annual charity event that raises funds for research into genetic disorders, especially neuromuscular diseases) and public subsidies, the product was subsequently developed by the US biotechnology company AveXis (14). In May 2018, Novartis bought AveXis for $8.7 billion (€7.4 billion) and set the price for Zolgensma° at about $2.1 million per child (€1.9 million), a major obstacle for American families (**b**)(14,15).

Pharmaceutical companies seeking the highest possible price: a strategy worth analysing and monitoring

In France, a report by the Court of Auditors (*Cour des Comptes*) noted how pharmaceutical companies' strategy changed in the 2000s, when the patents on many drugs of chemical origin for the treatment of common diseases had expired and tighter controls on health spending were introduced in the most economically developed countries. Companies shifted their focus to biological products and niche diseases with (our translation) "*higher economic potential*", in particular by buying up biotech companies rather than investing in their own in-house R&D (15).

Typically, the rights to use discoveries derived from publicly funded research are transferred to private corporations through an exclusive licence that provides modest royalties for the public institution that made the discovery and huge profits for the company (3).

As stated in the French Court of Auditors' report, pharmaceutical companies also revised their pricing strategy, basing them on the ability of public-sector buyers and insurers to pay, rather than on the sums invested in R&D. The aim is to get a return on their "investment" as soon as possible (15). The Court of Auditors cited *sofosbuvir* as an example, with a price tag that clearly bears no relation to its R&D costs (15,16). The pharmaceutical industry nevertheless continues to stress the very high cost of R&D, as can be seen for example on the website of the French Pharmaceutical Companies Association (17).

Ensure that the public stops paying for drugs twice

Irrespective of their country of origin, the above-mentioned reports and studies all denounce: the lack of transparency and the piecemeal information concerning public funding granted for biomedical R&D; the fact that public funding is granted without demanding affordable drugs in return; the absurdity of providing financial support to develop drugs that are useful to pharmaceutical companies but do not necessarily address society's most pressing public health needs, etc. The authors of these reports and studies have made a number of proposals to help ensure that the public no longer pays for drugs twice, once for their R&D, then once again for their purchase or reimbursement (2,3,18).

In May 2019, the World Health Organization (WHO) adopted a resolution calling for greater transparency over drug pricing (19,20). But WHO member states did not vote for transparency as to the cost of pharmaceutical R&D, a resolution supported by many organisations including *Prescrire* (21).

In France, in November 2019, in keeping with this WHO recommendation and under pressure from non-profit organisations, the government proposed a new requirement for pharmaceutical companies to tell the Economic Committee for Health Products (CEPS) how much public investment they received for the R&D of drugs likely to qualify for reimbursement or approval for hospital use (22). But unfortunately, the Constitutional Council quashed this measure on procedural grounds, without ruling on its merit (23,24). One year later, in October 2020, the same measure was about to be added to the law, with practical details still to be worked out (26).

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***b*-** *According to Novartis, the price is justified because the treatment consists of a single injection, whereas nusinersen (Spinraza°), authorised for the same disease, costs the French national health insurance system €420 000 per patient in reimbursements for the first year of treatment and €210 000 per year thereafter, for life (ref 14).*

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Oxycontin®: regulation conferred protection in some states in the US

● Internal documents suggest that promotion of Oxycontin® (*oxycodone*) by the company Purdue was lower in states with more restrictive prescription regulations. The increase in the number of deaths from opioid overdose was much lower in these states than in the other states.

Purdue used various strategies for the massive and aggressive promotion of Oxycontin® (*oxycodone*) in the United States, including: targeting doctors who were high prescribers of opioid drugs, financing "continuing education" for healthcare professionals, mass advertising in medical journals, etc. (1). Some economists also suggest that the company adjusted the intensity of its marketing activities according to the local regulations in different US states (2).

According to internal company documents obtained at the time of legal proceedings, when Oxycontin® was launched in 1996, the company considered that the existence of specific prescription forms for this type of opioid in five states would present an obstacle to its prescription (2).

One copy of the form had to be kept by the prescribing doctor, another by the pharmacy, and a third had to be sent to a state drug monitoring agency. These procedures, as well as concerns about government oversight, seemed to make doctors practising in these states more reluctant to prescribe Oxycontin®. It seems that the company therefore decided to market the drug less actively in these states (2).

In fact, in these five states, Oxycontin® was used less (for example, in 2000, 2.5 times less) than in states lacking this regulation. The number of deaths from opioid overdose also increased to a much lesser extent in these five states (2).

In light of the particularly harmful role played by opioid promotion in the huge epidemic of fatal overdoses observed between 1999 and 2015 in the United States, the authors of the study estimated that a regulatory framework similar to the one in these five states would have prevented two-thirds of the fatal opioid overdoses recorded in the other states (2).

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