R&D costs: secrecy at every level

• In France, the pharmaceutical industry has managed to turn a law to ensure transparency about the public funding it receives into a promotional opportunity.

Are new drugs expensive because of the high cost of research and development (R&D) borne by pharmaceutical companies?

Informed debate on the cost of pharmaceutical R&D is only possible if accurate and reliable figures are available, and if there is transparency, at the very least, about the extent of the public funds invested in R&D. In 2019, in response to pressure from various non-governmental organisations (NGOs) and Prescrire, the French government proposed that companies be required to inform its drug price setting committee (CEPS) of the "amount of public investment they have received for research and development" (our translation) for drugs eligible for reimbursement through the national health insurance system (1).

The legislation was passed in 2020, but the 2021 decree setting out its implementation reduced the scope of these declarations to direct public investments alone, exempting the research tax credits companies receive (2).

In late 2022, the CEPS published these figures for the first time in its 2021 annual report (3). Only 7 of the 190 companies that signed pricing agreements with the CEPS reported receiving public R&D funding in 2021. And the combined total of the sums they declared came to about €3 million (3). An alliance of NGOs denounced the figures as a "misleading representation of the reality" and evidence of substantial underreporting (4). LEEM, the association that represents pharmaceutical companies operating in France, claimed that it was not surprised, implying that the sums declared relate solely to clinical development (and not the research conducted beforehand) (5). This is an extremely narrow interpretation of the transparency about "public investment for research and development" provided for in the legislation.

Readers of the CEPS's annual report will also be surprised to learn that 18 companies declared having provided a combined total of about €49 million in funding for French public-sector research organisations, the main recipients being the National Institute of Health and Medical Research (INSERM) and university hospitals (3). This figure is published as a result of the framework agreement struck between the CEPS and the LEEM in 2021, "in the interests of transparency and information symmetry" (6).

In summary, the pharmaceutical industry has pulled off the trick of hijacking a transparency law relating to public R&D funding, in order to publicise its own funding of public-sector research, and with the cooperation of the CEPS to boot!

Pharmaceutical companies received about €700 million in indirect public funding for their R&D in 2019, through France's research tax credit scheme (7). More than 230 times the sums declared to the CEPS.

Would it really be so hard to require each pharmaceutical company to publish the financial help it receives through research tax credits? "In the interests of transparency and information symmetry" ...

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References

1- Prescrire Editorial Staff "Drugs research: public funding, private profits" *Prescrire Int* 2020; **29** (221): 303-306.

2- Prescrire Editorial Staff "Drug companies required to declare public funds received for R&D" *Prescrire Int* 2023; **32** (244): 26.

3- Comité Economique des Produits de Santé "Rapport d'activité 2021" December 2022: 232 pages.

4- Collectif d'associations "Transparence: quand la France demande aux entreprises pharmaceutiques plus de transparence, la réponse est toujours plus d'opacité!" 6 January 2023: 2 pages.

5- "Des ONG dénoncent la "sous-déclaration importante" des aides publiques perçues par la pharma" *APMnews* 6 January 2023: 2 pages.

6-CEPS and LEEM "Accord-cadre du 5 mars 2021 entre le Comité Economique des Produits de Santé et Les Entreprises du Médicament (LEEM)": 38 pages.

7- Ministère de l'Enseignement Supérieur et de la Recherche "Le Crédit d'Impôt Recherche (CIR) en 2020 (données provisoires)" August 2022: 4 pages.