Commentary: Reconsidering Pharmaceutical Research and Development Investments

Commentaire : Reconsidérer les investissements dans la recherche et le développement pharmaceutiques

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Abstract

Following Lee and colleagues' (2023) article explaining how Canadians are being shortchanged by drug companies when it comes to investments in research and development (R&D), this rejoinder adds context and appends two other very problematic elements in the debate between wishful narratives over the industry's contribution in R&D and actual numbers. First, even the current stricter definition of R&D investment might simply be too large considering that elements such as seeding trials – a well-known marketing device – can be accounted for as R&D expenditures. Second, this rejoinder identifies how Statistics Canada acted in concert with Innovative Medicines Canada to reinforce the industry's preferred narratives around R&D expenditures. This situation puts into question the trustworthiness of Canada's statistical agency.

Résumé

Suite à l'article de Lee et ses collègues (2023) expliquant comment les Canadiens sont bernés par les compagnies pharmaceutiques en matière d'investissements dans la recherche et le développement (R et D), cette réplique apporte du contexte et ajoute deux autres éléments très problématiques dans le débat entre, d'une part, les discours pieux sur la contribution de l'industrie dans la R et D et, d'autre part, les chiffres réels. Premièrement, même la définition la plus stricte de l'investissement en R et D semble tout simplement trop large, puisque des éléments tels que les essais cliniques promotionnels – un outil de marketing bien connu –

peuvent être comptabilisés comme des dépenses en R et D. Deuxièmement, cette réplique indique comment Statistique Canada a agi de concert avec Médicaments novateurs Canada pour renforcer les discours de prédilection de l'industrie concernant les dépenses en R et D. Cette situation remet en question la fiabilité de l'organisme statistique du Canada.

Overview

Lee et al. (2023) emphasize how, in spite of lobbyists' claims, Canadians are being shortchanged by drug companies when it comes to investments in research and development (R&D). There is nothing new in having drug lobbies push narratives to boast the "greatness" of their contribution to the Canadian economy, but a reminder about the discrepancy between wishful narratives and actual numbers is important.

Lee et al. (2023) argue that the ways Innovative Medicines Canada (IMC) and Statistics Canada use to calculate R&D investments are problematic and that these calculations should be made by adhering to the original definition of R&D investments, which includes R&D activities eligible for Scientific Research and Experimental Development (SR&ED) tax credits. The Patented Medicine Prices Review Board (PMPRB) uses the same definition, and drug companies have also committed to the 10% R&D-to-sales ratio based on this definition.

Should we narrow down the definition of R&D?

It must be asked if the current definition of R&D investment might simply be too large. Considering that R&D investments in the Canadian pharmaceutical sector benefit from generous tax credits of around 48% (Gagnon 2012), it is important that what falls under the definition of R&D actually benefits Canadian taxpayers. The problem is that, too often, drug research is designed for marketing purposes, with no intent of producing any new or additional knowledge (Klemperer 2010; Matheson 2008; Sismondo 2018). This includes much of the "research" that qualifies for SR&ED tax credits.

An example of these practices would be post-marketing (or phase IV) clinical trials, ostensibly designed as a way to monitor drug safety and adverse effects over a large population. Post-marketing trials, however, are often used as "seeding trials" to alter physicians' prescribing habits, and the results often go unpublished (Hill et al. 2008; Kessler et al. 1994; Lexchin 2011). After analyzing 558 industry-sponsored phase IV clinical trials, Spelsberg et al. (2017) found that less than 1% of the studies could be verified as published in scientific journals. None of the studies reported any evidence of adverse drug reactions – an interesting observation, considering that these studies were seemingly designed, at least in part, to report adverse events. These post-marketing trials are costly as the company will pay physicians a median remuneration of $300 (€200) for each patient they prescribe the new and more expensive product to (Spelsberg et al. 2017). In the PMPRB's "Patentee's Guide to Reporting" updated in 2015, these payments to doctors to influence prescribing habits without producing any relevant knowledge fall under the category of "other qualifying research" (PMPRB 2014) and can benefit from R&D tax credits. Phase IV clinical trials can

be relevant and important, but their current design by private companies to serve marketing purposes should not allow them to qualify as R&D. The same critique can be applied to many phase III clinical trials as well (Jureidini and McHenry 2020).

SR&ED is casting too wide a net

The current way of calculating R&D costs is highly complex, creating opportunities for third-party consultants to exploit loopholes in order to qualify activities that do not produce new or additional knowledge as tax credit-eligible R&D (Gagnon 2012). The 2011 Jenkins Report (Industry Canada 2011), which reviewed federal support to R&D, explained that Canada's basis for measuring qualifying R&D was wider than that of most Organisation for Economic Co-operation and Development countries. The report noted that too many non-R&D activities were qualifying to be included in the SR&ED definition of R&D, and as a result, it recommended narrowing down eligible R&D costs to labour-related R&D costs only (Industry Canada 2011).

In 2017, the Naylor Report (Advisory Panel on Federal Support for Fundamental Science 2017), which reviewed support for research in Canada, explained that even if the SR&ED program was downsized after the publication of the Jenkins Report (Industry Canada 2011), Canada remained an outlier by relying too much on indirect supports (tax credits) for R&D. The new report asserted that this approach was far from optimal, especially considering that the high profits of research companies following the application of tax credits were not translating into higher rates of R&D investments. Instead, the Naylor Report recommended relying more on direct public funding of R&D in order to be able to pull research in directions more in line with the public interest of Canadians. While the direct funding of R&D by the federal Liberal government slightly increased after the publication of the report (Owens 2022), the level of tax credits and the formula for the calculation of business expenditures in R&D were not significantly modified.

Statistics Canada: Siding with Big Pharma

With many ongoing debates highlighting the public policy impacts of the ways in which R&D is defined, it was more than surprising to see Statistics Canada publishing two consecutive reports in 2021 and 2022 (Statistics Canada 2021, 2022). The reports embraced the industry narrative regarding the need for the widest possible redefinition of R&D in the pharmaceutical sector. More surprisingly still, the results of the first report (Statistics Canada 2021) were published by mistake in an IMC (2021) press release on April 12, 2021 – one month before the publication of the report by Statistics Canada – revealing that the lobby group had privileged access to data and results.

In many ways, the reports published by Statistics Canada read much like uncritical infomercials for the pharmaceutical industry. With little apparent analytical consideration, these reports measure R&D investments, pharmaceutical companies' contributions to employment

and value added based on the widest possible definitions, as if these definitions had not already been widely criticized as problematic for the sector. These reports also do not mention or reference the high level of tax credits enjoyed by Canadian pharmaceutical sector companies. The contribution of the Canadian pharmaceutical sector is measured by adding up employment and value added that was created directly by drug companies indirectly (outsourced activities) or that was induced (payroll for direct and indirect employment allowing employees to spend money, which is implied to stimulate further positive gains in the economy). This calculation of induced impact implies that (directly or indirectly) employees in the Canadian pharmaceutical sector would not have been able to find employment elsewhere if these companies did not exist. Such an assumption is highly problematic, especially in times of acute labour shortage in the Canadian economy.

The Agreement between IMC and Statistics Canada

To understand the reasons behind such non-critical reporting by Statistics Canada, I used an Access to Information and Privacy (ATIP) request to obtain a copy of all the communications from January 2020 to May 2022 between Statistics Canada and the Canadian pharmaceutical drug lobby group IMC. The findings were somewhat troubling.

Based on the information released through the ATIP request, it appears that the two studies were commissioned by IMC for $161,072 ($85,649 for the first report and $75,423 for the second report) (Statistics Canada and IMC, personal communications, September 29, 2020 and September 16, 2021). Statistics Canada saw no apparent issue with using the numbers provided by IMC to publish reports that endorse the pharmaceutical industry's narrative about R&D investments.

In the letters of agreement between IMC and the minister of Innovation, Science and Economic Development (for the purpose of the *Statistics Act* [1985]), it was apparent that IMC maintained veto power over the reports, as it had the right to provide final approval over which indicators and concepts were to be used in the analysis. For example, in a communication between IMC and Statistics Canada on December 22, 2021 (document obtained through the ATIP request), IMC was concerned that Statistics Canada wanted to include the intensity measures for in-house R&D in section 2.2.2. This measure of R&D intensity is the above-mentioned R&D-to-sales ratio; the inclusion of these numbers would clearly show how IMC was shortchanging Canadians on R&D investments as compared with their commitments. In the communication dated December 22, 2021, IMC asserted that such an indicator "is not aligned with the scope of the work […] We would request it not to be included." Statistics Canada replied that they "will immediately action the changes." Accordingly, the final report (Statistics Canada 2022) does not include any mention of R&D intensity or R&D-to-sales ratio in section 2.2.2.

Conclusion

Lee et al. (2023) are right to claim that IMC's commitment to R&D investments is unfulfilled and that measures to redress broken IMC promises should be considered. However, by adding context and analysis, this rejoinder appends two other very problematic elements. First, it is important to initiate a thorough investigation into the nature of R&D in the Canadian pharmaceutical sector. While some R&D expenditures are indeed part of real efforts to achieve therapeutic advances, Canada's current basis for defining R&D allows the subsidization of marketing expenditures and financial incentives for influencing physicians' prescribing habits, such as seeding trials. A potential solution could be to allow R&D tax credits only for researchers' payroll, as recommended by the Jenkins Report (Industry Canada 2011), while increasing the direct public funding of R&D activities, as recommended by the Naylor Report (Advisory Panel on Federal Support for Fundamental Science 2017).

Second, the rejoinder identifies a seriously concerning intimacy between Statistics Canada and an industrial lobby group by showing how the federal agency acted in concert with IMC to reinforce IMC's preferred narratives around R&D. This situation is completely unacceptable. Statistics Canada must be able to build trustworthiness with all stakeholders, which requires providing information and data as neutrally as possible. Statistics Canada should never appear to be acting as a paid public relations agency for the industry or to uncritically promote narratives, indicators and concepts that serve commercial interests. By doing so in this case, Statistics Canada failed its explicit raison d'être (as explained on their website) of providing the trusted data, statistical services and insights required to support good decision making in public policy.

In this context, critical appraisal of the R&D investments in the Canadian sector, as proposed by Lee et al. (2023), is completely relevant and necessary.

Note

All currencies are in Canadian dollars unless noted otherwise.

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