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Incentivizing Biopharma Research and Development Innovation in Germany
(Recommendations from Sanofi)

Sanofi is dedicated to advancing global healthcare by intensively investing in research and development (R&D), with a global expenditure of 6.728 billion euros in 2023, [redacted]. To create a more attractive environment for R&D investment in Germany, it is essential to establish stable and innovation-friendly commercial conditions. This includes implementing reliable reimbursement conditions, conducive tax incentives, and competitive R&D frameworks.

NEED FOR RELIABLE AND STABLE GENERAL REIMBURSEMENT CONDITIONS

In a competitive global marketplace, having adequate reimbursement conditions is relevant to attract R&D investments. As an example, UK's challenging access environment for innovative medicines and vaccines has led to a 44% drop in patients enrolled in commercial clinical trials between 2021 and 2022, and a 21% reduction in inward FDI to £0.8 billion in 2023[1].

To enhance Germany's attractiveness for pharmaceutical R&D and avoid negative impacts seen in other countries, it is key to enhance the federal pharma strategy (e.g. manufacturers' discount for patent-protected pharmaceuticals fixed at 7%); abolish the Pharmaceuticals Market Reorganization Act's guard rails to link pricing to added benefit; and adopt a differentiated approach in AMNOG assessments based on therapy situations and industrial investments with greater flexibility in pricing negotiations.

NEED FOR CONDUCIVE TAX INCENTIVES BEYOND CURRENT DIRECT SUBSIDIES

Existing incentives in Germany are primarily focused on direct subsidies but can be further broadened to specific tax incentives with the following improvements

- **Tax subsidies: Uncapped R&D Credit or Super Deduction Mechanism**

  Germany's R&D tax credit has notable limitations, including a cap at 1M€, or 2.5 M€ for large groups[2]. Offering uncapped R&D credits or super deduction mechanisms are effective to attract local investments in R&D. For instance, France, a best-in-class example, offers a tax credit of 30% for eligible R&D expenses up to 100M€ and 5% for amounts above[3], while Italy provides a super deduction of 110% for R&D expenses linked to specific intangible assets[4]. Some countries can go up to 200% of eligible expenses[5]. These tax credits can also be converted into cash refunds if not utilized against corporate income tax within a few years.

- **Patent Box: Tax Bonus for Profits Generated by Intellectual Property**

  Patent Boxes (corporate tax rates reductions on net-income derived from use of intellectual property) create a strong incentive to localize more R&D activity, which in turn leads to further reinvestment in the local economy (tax revenues) and talent attraction. Currently, 13 of the 27 EU Member states have a Patent Box in place[6].

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[1] O'Shaughnessy J, Commercial clinical trials in the UK: the Lord O'Shaughnessy review – final report, 2023. Available online at: https://www.gov.uk/government/publications/commercial-clinical-trials-in-the-uk-the-lord-oshaughnessy-review/commercial-clinic (accessed September 2024)

[2] Maximum R&D tax credit per year: 1 million € by 2023 and 2.5 million € from 28.03.2024 (Growth Opportunity Act)

[3] Direction generale des Finances Publiques, The Research Tax Credit (CIR)

[4] OECD. Innotax. Italy: Tax allowance for R&D expenses related to eligible intangible assets, https://stip.oecd.org/innotax/incentives/ITA7

[5] https://taxfoundation.org/research/all/global/rd-tax-credit-rd-tax-subsidies-oecd/

[6] Tax Foundation, Patent Box Regimes in Europe 2024, https://taxfoundation.org/data/all/eu/patent-box-regimes-europe-2024/

- **Corporate Income Tax**

  Germany has one of the highest Corporate Tax Income rates in the EU (30% vs 25% EU average). To make the German taxable framework more attractive and competitive, a maximum 25% target for taxation of Corporates is essential.[7]

- **Reducing Bureaucratic Burdens**

  Bureaucracy should be reduced and a change to a risk-oriented and more trust-based tax audit approach should be implemented.[8]

NEED FOR MORE COMPETITIVE R&D FRAMEWORKS

Germany has made significant strides with the Medical Research Act, but further efforts are needed to enhance clinical trials and data-based R&D.

While Germany is the 4th biggest market for Sanofi after USA, China and Japan, it is far behind with regards to clinical trials. Germany ranks last in terms of the length of contract negotiations for clinical trials, taking between 128-298 days, compared to other EU countries, which never exceed 173 days. For instance, France completes negotiations in just 24-76 days[9]. To increase competitiveness in attracting clinical trials, Germany needs to harmonize clinical trial procedures within federal states and at the European level to shorten the length of negotiations. Swift implementation of the Medical Research Act's authorization for binding standards is also essential.

Further, improvements for data-based R&D are necessary. The Health Data Use Act ("Gesundheitsdatennutzungsgesetz") and the European Health Data Space are important regulatory milestones that can help Germany catch up with the digital transformation of its health system. Germany should focus on improving the quantity and quality of available health data, integrating further health data sources (e.g. historical health data) into a public research infrastructure (in addition to the Research Data Centre - "Forschungsdatenzentrum"-), and investing in digital infrastructure and electronic patient records.

[redacted]

[7] Abschlussbericht der Expertenkommission „Vereinfachte Unternehmensteuer" eingesetzt vom Bundesministerium der Finanzen, Juli 2024, S. 14 ff.
[8] Abschlussbericht der Expertenkommission „Vereinfachte Unternehmensteuer" eingesetzt vom Bundesministerium der Finanzen, Juli 2024, insbesondere 6. Digitalisierung, Prozesse 6. und Betriebsprüfung
[9] https://www.vfa.de/de/arzneimittel-forschung/forschungsstandort-deutschland/vfa-umfrage-lange-vertragsverhandlungen-klinische-studien-deutschland