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EUROPEAN INVESTMENT IN SEXUAL & REPRODUCTIVE HEALTH R&D: STEADY OVERALL, BUT ROOM TO GROW

This snapshot offers an up-to-date insight into European support for sexual & reproductive health (SRH) issues biomedical research & development (R&D) across the five years covering 2018 to 2022. Data has largely been drawn from two key projects through <u>Policy Cures</u> <u>Research</u> which track the R&D landscape for SRH: the <u>G-FINDER</u> project, which tracks and reports annually on the landscape of investment into low- and middle-income country (LMIC) appropriate R&D for new products and technologies to address a range of global health challenges, including SRH; and the <u>Accelerating Innovations for Mothers</u> project, which collects comprehensive data on the R&D pipeline for a number of critical maternal health conditions where biomedical product gaps exist. Data for this report was also drawn from the <u>Calliope Contraceptive</u> <u>Pipeline Database</u> and the <u>iMPT Product Development Database</u>, which collect data on the R&D pipeline for contraception and multipurpose prevention technologies (MPTs), respectively.

Key takeaways

- Europe plays a critical role in sexual & reproductive health R&D. Its level of financial investment is second only to the US – albeit by quite a margin – with European institutions and organisations involved in the development of a considerable number of LMIC-appropriate sexual & reproductive health technologies.
- Across all sectors, a large proportion of European funding comes from the UK (40%), without which total investment from Europe is notably reduced. Furthermore, public sector funding in Europe, excluding the UK, has declined by 26%, suggesting the need for reinvigorated interest and investment from a number of European governments.
- Industry within Europe contributes a robust level of funding, however 99% of its investment is provided by just five multinational pharmaceutical companies.
- Maternal health conditions, such as preeclampsia/eclampsia and postpartum haemorrhage, comprise less than 1% of European sexual & reproductive health funding, echoing a lack of global support for maternal health generally, and reinforcing a pressing need for renewed focus in this area.

Europe is a major player, but in a different league

European¹ funding for LMIC-appropriate sexual & reproductive health R&D² from all sectors totalled \in 1.256b from 2018 to 2022. Overall funding levels have remained fairly steady during this period, rising from a low of \in 225m in 2018 to a high of \in 268m in 2019, before averaging out at \in 254m between 2020 to 2022. Collectively, all sector European funding over this five-year period equated to 13% of the global total. While this was second only to the US, it is not a close second: the US provided a huge 82% (\in 7.779b) of funding to SRH within the same timeframe.



Figure 1: Global funding of sexual & reproductive health R&D by geography 2018-2022 (all sectors)

The UK plays an outsized role, without which funding is considerably smaller

Of the European funding reported from 2018 to 2022 through G-FINDER, and across all sectors (public, private and philanthropic), 40% of funding came from the UK (€500m). More than 70% of this funding from the UK came from the private sector (€359m, 72%), with public investment accounting for just 22% (€112m) and philanthropic investment the small remainder (€29m, 5,8%).

¹ For the purpose of this review, the term 'European' includes funding from the EU, bilateral funding from individual EU countries, as well as the UK, Switzerland, Norway, Iceland and Lichtenstein, as captured and available through the G-FINDER survey. ² For the purpose of this review, funding for sexual & reproductive health issues covers investment in R&D for LMIC-appropriate biomedical products for the following issues captured through the scope of the G-FINDER survey: HIV/AIDS, hepatitis B, HPV and HPV-related cervical cancer, other STIs, contraception, MPTs, postpartum haemorrhage, pre-eclampsia/eclampsia and non-issue specific funding (core-funding, platform technologies and other R&D). Overall, UK funding has dipped from its peak of €114m in 2019 (down €22m, -19%), though this fall is less steep than that from other European countries, and comes from a higher starting point.



Without the UK, SRH investment from Europe totalled \in 755m from 2018 to 2022. In comparison to the UK, funding was split almost evenly between the private (50%, \in 379m) and public sectors (48%, \in 361m), with philanthropic funding comprising just 2,1% (\in 16m). Funders from Germany made up the largest share (\in 228m, 30%), followed by Belgium (\in 196m, 26%) and France (\in 124m, 16%). The European Commission (EC) provided \in 90m (12%).

While Germany provided the highest amount of European funding outside of the UK, these levels have dropped by almost 75% from a peak of €78m in 2019 to €20m in 2022 (down €58m, -74%). France's funding experienced a fall of similar proportions over the same period, falling from €32m in 2019 to €10m in 2022 (down €22m, -69%). In contrast, Belgium's funding rose from €9,3m in 2018 to €74m in 2022 – entirely due to an increase in industry funding. The EC's funding has remained relatively stable.

Layers of neglect persist, with maternal health conditions worst off

European funding for SRH conditions at $\in 1.256$ b is relatively small when compared to other disease areas: across the same five-year period, European funding for neglected diseases totalled $\in 4.582$ b, and emerging infectious diseases totalled $\in 5.144$ b, with COVID-19 receiving $\in 3.710$ b alone. The evident neglect of SRH R&D is a trend that is not unique to Europe however, with SRH issues and women's health consistently failing to secure the levels of support and investment experienced by other global health areas, despite their associated high morbidity and mortality and potential return on investment.³

³ McKinsey & Company, "Closing the women's health gap: A \$1 trillion opportunity to improve lives and economies". January 2024

Moreover, of total European SRH funding, just under half was dedicated to HIV/AIDS (€593m, 47%). Funding for HIV/AIDS, which has benefited from years of strong global advocacy, is orders of magnitude higher than all other SRH issues, including all other STIs. Indeed, combined European funding for other major STIs, including hepatitis B, chlamydia, gonorrhoea, syphilis, herpes simplex virus-2 (HSV-2) and HTLV-1 (as well as other lesser known STIs and R&D for multi-STI products) was €275m. These STIs have experienced significant rises in funding from Europe since 2018 (up 230%), however their collective total is still less than half that dedicated to HIV/AIDS R&D.



Figure 4: European funding of sexual & reproductive health R&D by disease 2018-2022

Similarly, contraception R&D received just \in 158m in funding from Europe across the five years, and this declined from a peak of \in 48m in 2020 to \in 11m in 2022. Non-issue specific funding (including corefunding and funding of platform technologies) did rise from \in 6,9m in 2018 to \in 47m in 2022 – though totalling less than contraception over the five-year period at \in 129m. Funding for HPV and HPV-related cancers and multipurpose prevention technologies, while fluctuating, averaged just \in 17m and \in 1,7m for the five years, respectively.

Ultimately, however, it was the maternal health conditions, preeclampsia/eclampsia and postpartum haemorrhage (PPH), that were most neglected, receiving just 1% of an already limited pool of European SRH investment. This equated to €5,1m for each condition between 2018 and 2022. Over this time period, Europe accounted for just 4,6% of global preeclampsia R&D funding, though 25% of PPH funding. Lack of interest in maternal health R&D is not limited to Europe, with depressingly low investment in maternal health R&D globally overall.

The maternal health conditions preeclampsia/eclampsia and postpartum haemorrhage comprise less than 1% of European SRH funding, reflective of their lack of funding globally and suggesting a need for greater focus in this area.

Private sector investment is encouraging, but reliant on a handful of players

Almost 60% of European SRH funding came from the private sector (\in 738m), with its funding rising in both absolute and proportionate measures: from \in 125m (56%) in 2018 to \in 169m (67%) in 2022. Moreover, European companies accounted for 48% of total private sector SRH funding, with the US accounting for almost all of the remainder (50%). While this paints an encouraging picture of investment from European industry, funding is heavily concentrated: five multinational pharmaceutical companies contributed almost all European private sector funding (99%), with the remaining share provided by eight small pharmaceutical and biotechnology companies.

Interestingly, just under half of private sector funding came from the UK (€359m, 49%), but Belgium also accounted for a significant share (€194m, 26%). The remaining private sector funding came from pharmaceutical businesses in Germany (€150m, 20%) and France (€34m, 4,7%).



Figure 5: European funding of sexual & reproductive health R&D by sector 2018-2022

Perhaps unsurprisingly given its overall dominance, European private sector investment focused on HIV/AIDS, accounting for 48% of total private sector funding (€352m), almost all of which was directed towards drug development. Contraception accounted for the next largest share (€152m, 21%), with private investment peaking at €46m in 2019 before dropping to €11m in 2022. HSV-2 also received a large €111m of private sector funding, which accounted for almost three-quarters of worldwide HSV-2 funding captured in the G-FINDER survey across all sectors. Industry funding for HSV-2 may be driven by the primary goal of delivering improved products for high-income country markets, with the benefit to LMIC populations being a byproduct of this.

European interest in the maternal health R&D pipeline

One-quarter of postpartum haemorrhage (PPH) devices and medicines in the R&D pipeline (16 candidates) have evidence of European developer involvement. This rose as high as 33% (2 candidates) for PPH biologics and 33% (6 candidates) for PPH drugs (i.e., small molecule therapies), with the latter including a heat-stable orally disintegrating formulation of oxytocin developed by the Dutch Oxytone Bioscience. In comparison, dietary supplements have just 1 candidate (7,1%) with evidence of European developer involvement, whereas PPH devices have 7 candidates (28%), including the PPH Butterfly, an intravaginal device developed by the University of Liverpool.

For preeclampsia/eclampsia, one-third of medicines (53 candidates) have a European developer involved. Forty of these are repurposed medicines such as methyldopa and the probiotic Lactobacilli, with 13 candidates being new chemical entities. New chemical entities includes TRV027, an AT1 receptor agonist studied by the University of Zurich, and Kynurenine, a small-molecule drug being tested by Tommy's in preclinical studies.



European developer involved
No European developer involved

A number of marketed products have also been supported by European developers and investment. For example, Carbetocin – both its original and heat-stable formulations – was developed by Switzerland's Ferring Pharmaceuticals. Heat-stable carbetocin was added to the WHO essential medicines list in 2019, and was first approved in 2020 under the Swissmedic procedure for scientific advice and Marketing Authorisation for Global Health Products (MAGHP), intended to fast-track access to essential medicines in LMICs. It is currently being rolled out in India.

The PPH and preeclampsia/eclampsia R&D pipelines were curated by Policy Cures Research under the Accelerating Innovation for Mothers (AIM) project. It includes all pipeline products registered and candidates in development from 2000 to 2023.

The remaining 16% of private sector funding was split across HPV/HPV-related cervical cancer, gonorrhoea, chlamydia, hepatitis B, postpartum haemorrhage and non-issue-specific R&D. Private sector funding for postpartum haemorrhage all came from the UK, however this has declined from \notin 2,5m to just \notin 9k – demonstrating the generalised neglect experienced by maternal health conditions.

Philanthropic sector a minor player in Europe

European philanthropic sector investment into SRH R&D was limited, accounting for just 3,5% of European SRH funding over 2018 to 2022. There were just eleven philanthropic organisations, with three accounting for 90% of philanthropic funding: Wellcome (45%) and Children's Investment Fund Foundation (CIFF) (20%) both from the UK, and Fundació La Caixa (25%) from Spain.

Declines in bilateral funding call for reinvigorated European government investment

European public funding, nearly all of which was via government investment, accounted for 38% of total European SRH R&D funding, and 7,1% of global public sector SRH funding. However, European public funding for SRH R&D has dropped from a peak of €125m in 2019 to €74m in 2022 (down €51m, 41%).

The UK government's support, which accounted for around one-quarter of European public sector funding from 2018 to 2022 (€112m, 24%), dropped by 75% from its 2019 peak of €39m. Outside the UK, the largest shares of public funding came from the EC (€90m), France (€89m) and Germany (€78m). France and Germany's funding have also dropped, by 83% and 71% respectively from their

European Commission funding in 2023

In 2023, the EC's SRH R&D funding totalled €20m. At this level, it sat €2m above its average over the past five years, though below the €23m peak in 2020. In 2023, the EC disbursed funds to 147 recipient organisations for six SRH areas: platform technologies (€12m, 59%), hepatitis B (€3,8m, 19%), HIV/AIDS (€2,3m, 11%), HPV and HPV-related cervical cancer (€1,2m, 5.8%), other non-issue-specific SRH R&D (€0,6m, 2.9%) and STIs (€0,4m, 1.8%), including syphilis and trichomoniasis. In the past, the EC has also provided funding for contraception (€2,8m since 2018) and pre-eclampsia/eclampsia (€2,4m since 2018), however this funding ended in 2021 due to the conclusion of projects.





2019 peaks. Reductions in funding from these two heavyweights were accompanied by smaller falls from the public sector in other European countries, including Denmark and the Netherlands. Overall, this drove public funding – mostly bilateral support – from non-UK European countries to fall by 26%, suggesting the need for reinvigorated public sector interest and investment.

However, a few European countries did buck the downward trend. Spain's public funding rose from just €0,1m in 2018 to €6,4m in 2022. The Czech Republic was the second-highest public European funder in 2022, disbursing €15m to establish its National Institute of Virology and Bacteriology (although this represents expenditure relevant for SRH R&D alongside neglected disease and emerging infectious disease R&D). Furthermore, the EC's funding has stayed relatively stable, even rising in the two years to 2023 (see box-out on previous page).

The European public sector funded a broader range of SRH issues than the private sector. HIV/AIDS again received the largest share of funding (\in 220m, 46%), however funding also concentrated on non-issue-specific R&D (\in 117m, 25%), entailing core funding of organisations that conduct SRH R&D (\in 68m, 14%), platform technologies (\in 38m, 8.0%) and other R&D targeting multiple SRH issues or SRH issues in combination with NDs and EIDs (\in 11m, 2,4%).



Figure 6: European public funding of sexual & reproductive health R&D by country and disease 2018-2022

Almost all the European preeclampsia/eclampsia funding came from the public sector, with its contributions totalling \in 5,0m. Most of this came from the EC and Sweden, however there were smaller contributions from the UK, Germany, Austria and Hungary. The UK and Ireland were the only countries to publicly fund PPH R&D, while the EC contributed over 80% of the public contraception funding – though this equated to less than 2% of total European contraception funding, with 95% of this coming from the private sector.

European interest in contraception and MPT R&D

European developers are involved in the development of 37 out of 191 contraception products in the R&D pipeline (19%), including 20 products in discovery & preclinical development, and 17 products in clinical development. UK developers have the largest portfolio of contraception products under development (12 candidates), including microarray patch delivery of hormonal contraception by Queen's University Belfast and progestin cream by Viramal, an Ango-Scandinavian pharmaceutical company. Following the UK, Germany has the highest number of contraception products under development (10 candidates), then France (7 candidates) and Sweden (4 candidates).



Box-out figure 1: Contraception with European developer involvement

Of the 24 multipurpose prevention technology (MPT) products under active development, just two (8,3%) have European developer involvement – both in preclinical stages. These include an intravaginal ring developed by Queen's University Belfast, alongside Population Council and Weill Cornell Medical College, designed to protect against pregnancy and STIs. It also includes a new vaginal delivery system developed by researchers at CESPU, i3S and the University of Porto, and funded by the Portuguese Foundation for Science and Technology. This vaginal delivery system incorporates tenofovir and efavirenz nanoparticles into a polymeric film base to protect against HIV, HSV-1 and HSV-2.



Box-out figure 2: MPTs with European developer involvement

Information on the contraception products under development was taken from the <u>Calliope Contraceptive Pipeline</u> <u>Database</u>, coordinated by FHI 360 as part of the Contraceptive Technology Innovation (CTI) exchange. It includes all contraceptive candidates that have been under development with no time-frame restrictions. Information on the MPTs under development was taken from the <u>iMPT Product Development Database</u>, coordinated by iMPT, a project of CAMI-health. It includes all candidates that are currently funded and in active development as of September 2023.

European developer involved No European developer involved

The 2023 sexual & reproductive health G-FINDER report, <u>Beyond Spillovers</u>, provides a comprehensive picture of global investment into R&D for SRH products and technologies that are applicable to low- and middle-income country settings.

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