

Spotlight on pharmaceutical companies' actions in women's health & SRHR: Looking back & moving forward

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Women in low- and middle-income countries (LMICs) are deeply affected by a lack of access to essential health products, and in particular products related to their sexual and reproductive health and rights (SRHR). This situation reflects a longstanding failure to ensure that such products reach the women who need them. For many years, the Access to Medicine Foundation has been assessing and tracking the performance of research-based pharmaceutical companies in expanding access to their products in LMICs, and looking at whether they are developing new products that address R&D priorities and the needs of the most vulnerable populations.

In November 2022, the Foundation will publish the next Access to Medicine Index, which will include a special report focused on pharmaceutical companies' actions to improve women's health and SRHR. This paper looks ahead to that special report, and looks back over previous findings about SRHR and women's health to shed light on why more action from companies is urgently needed.

INTRODUCTION

Women in low- and middle-income countries (LMICs) lose out when it comes to sexual and reproductive health and rights (SRHR) – and a core problem is their lack of access to the essential health products they need. For example, approximately 90% of those who die from cervical cancer are women living in LMICs, and most of those deaths would have been preventable through immunisation. A lack of access to treatments for dangerous conditions such as hypertensive disorders of pregnancy, maternal sepsis, obstructed labour, miscarriage, endometriosis, and uterine cancer can have a huge impact on women's quality of life, and can ultimately be life-threatening. Unfortunately, the knock-on effects of the COVID-19 pandemic have made an already challenging situation worse, for example by disrupting HPV vaccination programmes, postnatal care, and access to family planning services.

The UN's Sustainable Development Goals (SDGs) should be achieved by 2030, and the global health community is working towards this ambition. But unless pharmaceutical companies and other global health stakeholders step up to increase access to medicines, vaccines and diagnostics in LMICs, it will not be possible to reach many of these goals – especially Goal 3, which is to “ensure healthy lives and promote well-being for all at all ages.” This encompasses targets including reducing maternal mortality and granting universal access to sexual and reproductive care.

The Access to Medicine Foundation has been tracking company action on SRHR as part of the Access to Medicine Index for more than a decade, assessing the state of play and closely examining the evolving ecosystem around access to medicine. This paper highlights some encouraging examples of recent announcements made by pharmaceutical companies and reiterates the need for companies to step up their efforts to address access issues that have now been exacerbated by the COVID-19 pandemic. These efforts include expanding research and development (R&D) to address treatment gaps, ensuring access to existing health products in LMICs, and mitigating the fallout of the COVID-19 pandemic on women's health. This paper will be followed up with a data-driven special report on SRHR in the 2022 Index, due in November.

Defining SRHR

The Foundation defines SRHR as the efforts to eliminate maternal morbidity and mortality; ensure high-quality sexual reproductive health services, including contraceptive services; address sexually transmitted infections (STIs) and cancers related to reproduction; and address the sexual and reproductive health needs of women and adolescent girls (encompassing the health needs of all individuals assigned female at birth). SRHR also refers to women and girls' freedom from sexual violence, coercion, and discrimination.

URGENT PROBLEMS IN WOMEN'S HEALTH AND SRHR

The burden of sexual and reproductive ill-health is overwhelmingly borne by women living in LMICs. Sexual and reproductive health specific diseases, conditions and pathogens account for one fifth of the burden of disease among the global population, and one third of the global burden of disease among women of reproductive age globally.

Looking at facts and statistics from prior to the COVID-19 pandemic, the scale of the longer-term problem is clear. We know that:

- 250,000 young people aged 15-19 were newly infected with HIV each year, of whom almost two thirds were female – rising to three quarters in sub-Saharan Africa.
- Women living in LMICs accounted for around 94% of maternal deaths, with more than 800 women dying during or following childbirth every day – mostly in sub-Saharan Africa.

- Approximately 214 million women of reproductive age living in LMICs had unmet needs for modern contraceptives, contributing to 111 million unintended pregnancies each year. Fully meeting contraceptive needs would avert up to 76 million unintended pregnancies, 46 million induced abortions and 70,000 maternal deaths annually.
- There were 570,000 new cases and 311,000 deaths from cervical cancer in 2018.

There are many factors and deep-rooted issues that can cause poor health outcomes for women living in LMICs, such as the stigma around certain diseases, or the rights of women to access necessary healthcare. However, ensuring access to essential health products could significantly improve the situation – and drive these numbers down.

IMPACT OF THE COVID-19 PANDEMIC

Studies of previous health crises, notably the HIV/AIDS pandemic and the Ebola and Zika epidemics, showed that countries with less-resilient health systems can experience indirect mortality effects, such as death from unsafe abortion due to closed clinics, just as significantly as direct mortality effects – i.e., people dying from the disease.

The COVID-19 pandemic has indeed impacted women's health and SRHR both directly and indirectly across LMICs. In terms of direct effects, pregnant women have been particularly impacted by COVID-19, especially when unvaccinated for the disease. In terms of indirect effects, the time and resources of healthcare professionals have been redirected towards tackling the COVID-19 pandemic, leading to notable gaps in the continuum of care and therefore missed opportunities to prevent illness, treat its effects, and mitigate risks associated with pregnancy.

With healthcare systems and supply chains under strain, especially at the start of the COVID-19 pandemic and during its peaks, there was a reduction in access to essential services, medicines and vaccines for women's SRHR. There were disruptions to family planning services and closures of abortion clinics, which led, for example, to the reduction of safe abortion services and comprehensive abortion care by up to 47.1% in Nepal. Other effects included disruptions to screening, testing and treating for uterine and breast cancer; for example, cancer treatments were temporarily discontinued during COVID-19 surges in countries including Cameroon, Bangladesh, India, Honduras and China. The proportion of girls globally with access to HPV vaccines declined from 15% pre-pandemic to 13% by late 2021.

Intertwined with this was the impact on women and girls' health-seeking behaviours – i.e., whether they sought necessary medical attention. Discouraging factors included fears of contracting COVID-19 while accessing health services, and restrictions on travelling to clinics during strict lockdowns.

The challenges posed by the COVID-19 pandemic have only exacerbated existing long-term issues in women's health and SRHR. These include regional accessibility gaps, issues with long-term affordability, stigma, misinformation, government rulings and a lack of product choice to improve uptake and continued use.

SRHR AS A GLOBAL HEALTH PRIORITY

In the years leading up to the pandemic, international organisations and national governments emphasised the importance of women's health and SRHR in LMICs and made it a priority via funding and other initiatives. For example:

- The first international Family Planning Summit was hosted by the World Health Organization (WHO) in London in 2012. This set the stage for increased attention, funding and action from pharmaceutical companies.
- Launched in 2016, The Challenge Initiative is a “business unusual” platform led by the Bill & Melinda Gates Institute for Population and Reproductive Health at Johns Hopkins Bloomberg School of Public Health. It aims to empower local

governments to rapidly and sustainably scale best-practice reproductive health solutions to benefit urban poor communities.

- Over the last decade, many high-income countries have prioritised SRHR in their foreign aid contributions, including including Canada, Germany, the Netherlands, Norway, Sweden, the UK, and the US. These countries, among others, have provided major funding in support of global vaccination campaigns against HPV; maternal health care; family planning; and treatment for sexually transmitted diseases.

There are encouraging indications that the momentum on this topic has not been lost during the COVID-19 pandemic. In 2021, the [International Planned Parenthood Federation](#) hosted a G7 SRHR Ministerial Roundtable. At the roundtable, representatives from Canada and Japan called for an integrated and collective effort to better enable health systems to respond to the pandemic, while ensuring bodily autonomy and SRHR remain indispensable and integral components of UHC and the SDGs. The reaffirmation of the commitment to “ensuring that SRHR and bodily autonomy are central to reaching Universal Health Coverage (UHC) and the Sustainable Development Goals (SDGs)” signalled that, despite significant global health attention on the need to address the COVID-19 pandemic, SRHR remains a top priority on political agendas. Making progress on SRHR is critical in the fight against poverty, the pursuit of sustainable development, and the realisation of gender equality and the right to health.

HOW THE ACCESS TO MEDICINE FOUNDATION DRIVES PROGRESS ON WOMEN’S HEALTH AND SRHR

The Foundation is an independent not-for-profit organisation that assesses healthcare companies’ actions to improve access to medicine in LMICs, stimulates them to build on their positive actions, and holds them accountable to their promises. Drawing on insights from data, original research, and engagements with a range of stakeholders, the Foundation identifies key opportunities for each company to deliver change. The Foundation pursues these opportunities not just with the companies themselves, but also by mobilising coalitions of investors in pharmaceutical companies, and by working with governments and other global health stakeholders to help inform evidence-based policy decisions.

Since 2008, the Foundation has regularly published the Access to Medicine Index, which analyses how 20 of the world’s largest research-based pharmaceutical companies are addressing access to medicine. This ranks the companies, tracks progress, identifies best practice, and demonstrates where action is urgently needed to improve access to medicine for some of the world’s most vulnerable populations. As part of the Index, the Foundation looks at women’s health and SRHR, for example by examining the R&D pipeline for conditions affecting women and girls and identifying gaps in access to key healthcare products such as long-acting contraceptives, breast cancer treatments, and HPV vaccines. In 2015, the Foundation addressed the topic specifically in a paper on [‘Improving maternal health and access to contraceptives’](#), which looked more deeply at data from the Index and tracked companies’ commitments to action.

The Index now covers products related to five maternal health conditions, nine STIs and reproductive health conditions, and four cancer types. The [latest Index](#) highlighted 14 company-specific opportunities to improve women’s health and SRHR and identified concrete actions companies could take. In the upcoming Index, due for publication in November 2022, the Foundation will take a targeted approach, with a dedicated special report on the topic. This analysis will help policymakers, advocacy groups, investors, and the companies themselves to address critical gaps.

Disease scope of the Access to Medicine Index

5 Maternal health diseases and conditions: Hypertensive disorders of pregnancy, maternal abortion and miscarriage, maternal sepsis, obstructed labour, pre-term birth complications

9 STIs and reproductive health conditions: Contraceptive products, endometriosis, chlamydia, gonorrhoea, HSV-2, HTLV-1, syphilis, hepatitis B, HIV/AIDs

4 Cancers: Uterine cancer, ovarian cancer, breast cancer, cervical cancer

Looking beyond the research-based pharmaceutical companies, the Foundation is now expanding its work, as set out in the [Strategic Direction for 2022-2026](#), by mobilising more essential healthcare sectors and a broader range of healthcare companies to take action at the scale required. This move will enable the Foundation to centre around vulnerable populations, including women and girls, and to push for progress on women's health and SRHR across the entire continuum of care. Future work will include generic medicine manufacturers, LMIC-based manufacturers of vaccines (e.g. HPV vaccines), companies that produce diagnostics (e.g., for ovarian and cervical cancers), and medical gas companies that supply oxygen – a treatment that can be vital in so many medical situations, including childbirth.

LOOKING BACK: TRACKING THE PHARMA INDUSTRY'S INVOLVEMENT IN ACCESS TO MEDICINE

Pharmaceutical companies have an important role to play in access to medicine, firstly by developing new products to meet the needs of women and girls in LMICs, and secondly by ensuring widespread access to existing products in their portfolios. The Index, alongside other research from the Foundation, has identified key trends in how pharmaceutical companies are addressing women's health and SRHR with their products.

The development of innovative new healthcare products would play a significant role in improving women's health and SRHR. However, over 70% of internationally defined R&D priorities for LMICs remain unaddressed. In particular, the Foundation has consistently identified R&D gaps for products to treat women's health conditions and improve SRHR.

The Foundation's 2015 paper '[Improving maternal health and access to contraceptives](#)' found that all of the R&D initiatives being pursued by the companies in scope targeted post-partum haemorrhage – but that even these initiatives were very small in number. The Foundation's 2019 paper '[Are pharmaceutical companies making progress when it comes to global health?](#)' showed that, from 2014 to 2018, all R&D pipelines had grown for key diseases tracked by the Foundation, except those for maternal and neonatal health conditions, which marginally decreased from just 10 R&D projects to 9. Indeed, projects for maternal conditions remain highly underrepresented in companies' pipelines overall, accounting for only 1% of R&D projects within the scope of our research. By the 2021 Index, only four relevant maternal health projects were in the R&D pipeline: two for the treatment of post-partum haemorrhage and two targeting maternal sepsis.

The data also makes clear that, while there have been some approvals of new products to treat HIV/AIDS, there are few approvals for products for other SRHR-related conditions. [The 2019 paper](#) showed that HIV/AIDS medicines have the second highest number of approvals (34) of any product type, behind diabetes products (51), for the period 2008 to 2018; in the same period, only five new contraceptive products had been approved, all of them developed by Bayer.

Securing access to existing medicines for patients in LMICs is also key. Access strategies deployed by pharmaceutical companies can consist of a range of activities, including prioritising countries with the highest disease burdens for registration; developing equitable pricing strategies; committing to sufficient supply; issuing

or engaging in non-exclusive voluntary licences; and supporting donation programmes during emergencies. Such access strategies help facilitate the availability, accessibility, affordability and supply of products for patients living in LMICs.

In 2015, the Foundation's [maternal health and contraceptives report](#) looked at the access strategies used by the pharmaceutical companies in scope. The majority of these strategies focused on local capacity building in LMICs – a theme seen across several successive Index reports, which also highlighted capacity building initiatives and inclusive business models such as [Astellas' Action on Fistula Foundation](#), Boehringer Ingelheim's partnership with [Jacaranda Maternity](#) or the [Pfizer Foundation](#) and PATH's 'Scaling up Breast Cancer Services' programme.

Here, a few examples of from recent Index reports can be noted, indicating what companies have done in this area.

Pfizer was recognised with a [best practice](#) in the 2021 Index for its Patent Assistance Programme and equitable pricing approach in India and Mexico for palbociclib (Ibrance®), used to treat breast cancer. Novartis's emerging market brand strategy was also highlighted as a [best practice](#) in the 2021 Index, for its strategy that aimed to address the affordability of ribociclib (Kisqali®) for the treatment of breast cancer. The company launched its emerging market brands, which prices medicines at a significantly lower price than the global average for the original brand.

Recent Indexes have also identified other examples of access strategies used by pharma companies for SRHR-related essential health products. For example, in 2019, Eisai introduced a tiered pricing strategy for its breast cancer treatment eribulin (Halaven®) through its 'Hope to Her' programme. This was based on income levels and in partnership with third party administrators, in collaboration with Mylan (now Viatris). This programme included an affordable pricing model for the medicine in eight Asian countries, including Thailand and India.

As another example, the 2018 Index highlighted the 'Merck for Mothers' initiative. Through this programme, MSD (Merck & Co., Inc) worked in collaboration with Ferring Pharmaceuticals and WHO to support the advancement of Ferring's proprietary and investigational heat-stable carbetocin, for the prevention of postpartum haemorrhage – a drug well-suited to use in LMIC settings as it does not require refrigeration. This collaboration aimed to make the drug available at an affordable and sustainable price within the public sector in LMICs, and it has been approved and used in several countries in Asia and Africa.

LOOKING FORWARD: RECENT EXAMPLES OF COMPANY ACTIONS

Since the end of the period of analysis for the previous Index in May 2020,¹ several of the pharmaceutical companies in scope have publicly announced new commitments, projects or strategies for their products related to SRHR and women's health. Here, the Foundation notes some of these recent developments. A detailed analysis of such examples will be included in the special report on SRHR in the upcoming 2022 Access to Medicine Index.

Contraception

In 2020, Bayer announced a collaboration that aims to facilitate the scaling-up of family planning approaches for economically vulnerable populations in urban areas of LMICs. This followed on from the company's pledge at the 2019 Nairobi Summit that, by 2030, it will be satisfying the need for modern contraception for [100 million women in LMICs](#) each year.

¹ The period of analysis ended on 31 May 2020. The Index was published on 26 January 2021.

HIV prevention for women

Johnson & Johnson has partnered with the International Partnership for Microbicides (IPM) to develop and release dapivirine, an antiretroviral vaginal ring designed as a long-acting form of HIV prevention for at-risk women, particularly in LMICs. IPM has received regulatory approval in Zimbabwe and nearby countries, while the European Medicines Agency has recommended it for use in high-prevalence countries in addition to other HIV prevention methods.

In 2020, cabotegravir/rilpivirine (Cabenuva®), which is jointly developed by Johnson & Johnson and ViiV Healthcare, became the first long-acting injectable for the treatment of HIV infection to receive regulatory approval, first in Canada and subsequently in several other countries. The product is especially promising for women of reproductive age who are disproportionately impacted by HIV in sub-Saharan Africa.

Cancers related to women's health and SRHR

In 2020, Pfizer, under its [partnership](#) with Clinton Health Access Initiative (CHAI), expanded its pricing and access strategy for its breast and ovarian cancer medicine carboplatin to also include Malawi, Zambia and Zimbabwe.

Pricing strategies for HPV vaccines

Since 2020, GSK has provided its HPV vaccine Cervarix® to [Gavi, the Vaccine Alliance \(Gavi\)](#) at the lowest price tier of their pricing strategy, and has committed to freezing the price of the vaccine for countries transitioning out of Gavi.

MSD has supplied its HPV vaccine Gardasil® to Gavi since June 2020, and extended its current Gavi prices for Gardasil through 2025 to Gavi-graduated countries with a per-capita gross national income not exceeding USD 3,200. MSD has developed and launched Gardasil 9®, a 9-valent HPV vaccine, which is not currently purchased by Gavi.

Menopause treatments

In May 2022, Pfizer announced 'An Accord for a Healthier World', an initiative which aims to provide 23 of its patented medicines and vaccines on a not-for-profit basis to 45 low-income and lower-middle income countries. This includes Duavive™ (oestrogens conjugated/bazedoxifene), which is used to treat moderate-to-severe vasomotor symptoms (i.e. hot flashes and night sweats) after menopause.

WHAT NEXT?

It is critical that women living in LMICs are assured better access to SRHR-related health products, and it is likewise critical that new products are developed to meet their needs.

The examples shared above offer a snapshot of some of the most recent actions taken in these two areas by pharmaceutical companies. A more detailed picture will be provided by a special report on SRHR products in the upcoming 2022 Access to Medicine Index, alongside data-driven analysis. This will assess companies' performance on ensuring access to their SRHR-related products in LMICs, and whether they have any promising products in their R&D pipelines. The Index will also pinpoint new opportunities for pharmaceutical companies in this area, building on the Foundation's ongoing engagement with companies and other global health stakeholders about how to make access to medicine a reality for key SRHR-related products.

Over the past decade, there has been an increased emphasis on women's health and SRHR as a priority within the global health community, and there are indications that this emphasis has not waned in the past two years – despite global health funders' additional focus on addressing COVID-19 pandemic. However, there are also indications that the COVID-19 pandemic itself has had a negative impact on women's health and SRHR, worsening an already difficult situation for women. Existing momentum must not be lost, and greater momentum must be generated, in order to meet the goal to “ensure healthy lives and promote well-being for all at all ages” by 2030.

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ACCESS TO MEDICINE FOUNDATION

The Access to Medicine Foundation is an independent non-profit organisation based in the Netherlands. It aims to advance access to medicine in low- and middle-income countries by stimulating and guiding the pharmaceutical industry to play a greater role in improving access.

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