

Special Report Women's Health and SRHR

SPECIAL REPORT: WOMEN'S HEALTH AND SRHR

Sexual and Reproductive Health and Rights (SRHR) are human rights for all people. However, the ability to exercise these rights is not accessible for all. SRHR range from having access to safe, effective and affordable forms of contraception, access to skilled healthcare providers and services to support safe pregnancies and births, to access to treatments and products for various sexual and reproductive diseases and health needs. SRHR are a key component to achieving the Sustainable Development Goals (SDGs) set by the United Nations General Assembly and Universal Health Coverage set by the World Health Organization (WHO). To achieve these by 2030, action needs to focus on ensuring women and girls, no matter where they live, have access to medicines, products and services for sexual and reproductive health.

Although addressing SRHR requires global efforts from various stakeholders, pharmaceutical companies have a key role to play.

This Special Report in the 2022 Access to Medicine Index highlights critical areas where companies can do more to address access issues for SRHR-related diseases and health needs impacting women and girls. The diseases and health needs covered were selected based on existing definitions of SRHR, with a focus on those that disproportionately impact women and girls in low-and middle-income countries (LMICs). It examines the extent to which companies are conducting research on new products and formulations for SRHR-related health needs, as well as strategies companies are applying in LMICs to make products accessible through mechanisms such as registration and pricing strategies. The report also analyses company capacity building efforts and engagement in inclusive business models that reach women and girls living in LMICs.

CONTEXT

SRHR and women's health is a critical priority for expanding access to medicine

In the past half century, progress has been made to improve women and girls' access to SRHR (Sexual and Reproductive Health and Rights) products, services and information, but stark inequalities persist both within and between countries that prevent women from realising their full rights to health.¹ Particularly in low- and middle-income countries (LMICs), women's health services, specifically SRHR services, are often not provided at a level of quality that meets minimum medical and human rights standards.² The COVID-19 pandemic and related mitigation efforts have also disrupted access and utilisation of sexual and reproductive health services such as contraceptive services, testing for sexually transmitted infections (STIs) and safe abortion services.³

In many LMICs, women's ability to attain SRHR services may be impacted by several barriers, such as a lack of trained staff, limited access to epidemiological data, or inability to source or fund supply of medicines and contraceptives. These barriers exist alongside gaps in research and development (R&D) for some SRHR-related diseases and health needs, for example new products or adaptations that would be suitable for women living in LMICs.⁴

However, global shifts are in motion, with the United Nations identifying universal access to SRHR as a global health priority and its inclusion in the 2030 agenda for Sustainable Development.⁵

SRHR should be afforded to everyone regardless of gender. However, the Access to Medicine Foundation is focusing on women's health in this report given the impact of gender inequality on the sexual and reproductive health of women and girls and the need for increased focus and improvements within the space.⁷

Defining the scope of this Special Report on SRHR of women and girls

Under its broadest definition, Sexual and Reproductive Health and Rights include the rights to the prevention and treatment of sexually transmitted infections (STIs), including HIV/AIDS, and other genitourinary diseases; affordable and acceptable methods of contraception; effective services for healthy pregnancy and birth; prevention and management of reproductive cancers; safe abortion and post-abortion care; safe and hygienic management of menstruation; and management of sub-fertility, infertility and other fertility issues. It also extends to concepts of care and services related to sexuality and sexual and/or gender identity, sexual dysfunction, and gender-based and intimate partner violence.^{4,6}

TABLE 3 Products and R&D projects that target SRHR-related diseases and health needs

Of the 83 diseases and health needs in scope of the Index, 19 (23%) are related to SRHR. Of the total 1,060 projects in the pipeline, 171 (16%) address SRHR-related diseases and health needs and of the 740 products in the portfolio, 176 (24%) are related to SRHR diseases and health needs.

SRHR-related diseases and health needs in scope of the Index		Approved products in portfolio	R&D projects in pipeline
Hypertensive disorders of pregnancy		3	0
Maternal abortion and miscarriage		1	0
Maternal sepsis		3	2
Obstructed labour		0	0
Maternal haemorrhage		3	2
Contraceptive methods		17	1
Endometriosis		6*	3
STIs	Chlamydia	1*	2*
	Gonorrhoea	2*	3*
	HTLV-1	0	1
	HSV-2	0	0
	Syphilis	1	0
	Hepatitis B	17*	22
	HIV/AIDS	62*	30
M. genitalium		0	2*
Uterine cancer		0	13*
Ovarian cancer		17*	36*
Breast cancer		47*	62*
Cervical cancer (including HPV-related)		10*	20*
All diseases/health needs		176	171

*One or more of these projects/products may be indicated for multiple disease areas (e.g., a treatment for both endometriosis and cancer, or a diagnostic for both chlamydia and gonorrhoea) and therefore may be included more than once in the

table. The total overall number of products/projects is given in 'All diseases/health needs'.

RESEARCH & DEVELOPMENT

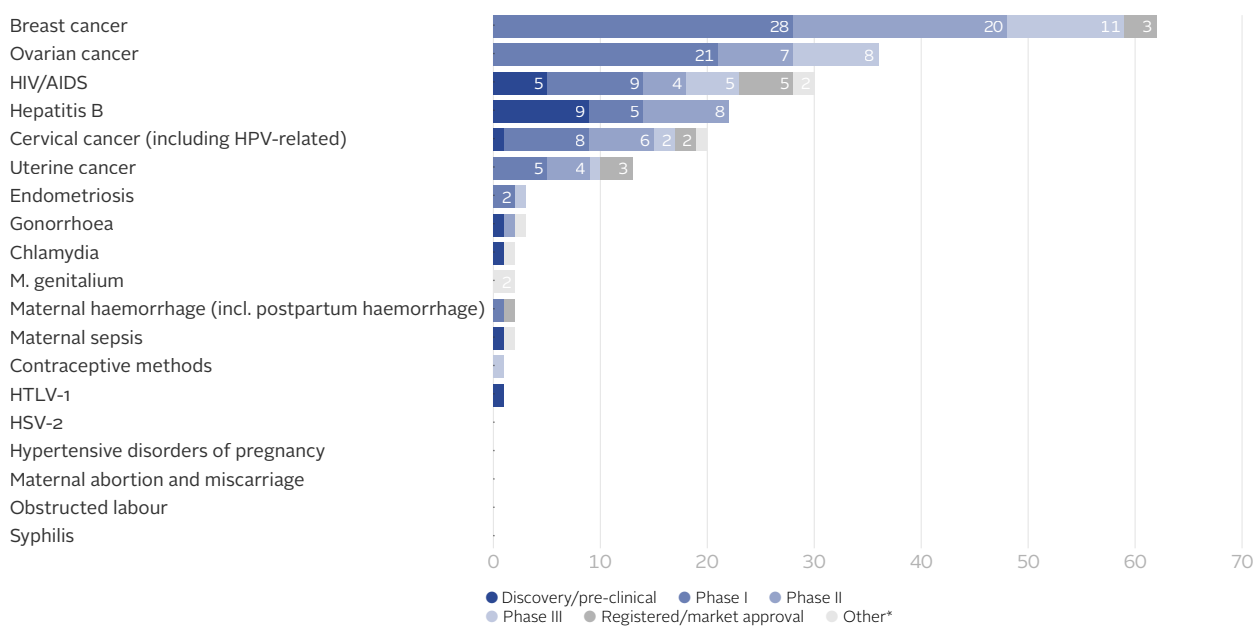
R&D projects and priorities for SRHR – what are companies doing to fill the gaps?

Cancers (i.e., breast, ovarian, cervical and uterine) are a well-addressed category within the SRHR-related diseases and health needs in scope of the Index, with 105 (60%) projects in the SRHR pipeline targeting one of these cancer types. However, of the four cancer types, breast and ovarian cancer account for the highest number of projects. This finding mirrors the makeup of the pipeline for all diseases in scope, where companies invest resources into developing products for non-communicable diseases (NCDs), where significant commercial potential is more likely in comparison to other diseases and health needs like contraceptives or maternal health conditions.

R&D for some SRHR-related diseases and health needs in scope of the Index is particularly under-resourced. For example, five diseases and conditions are not addressed at all by any R&D project. Conditions related to maternal health are especially underrepresented, with just four projects split between maternal haemorrhage and maternal sepsis.

FIGURE 17 **Almost all SRHR-related pipeline projects are directed towards cancer types, HIV/AIDS and hepatitis B**

All SRHR-related projects, split per phase of development.



Opportunities for R&D efforts to address specific therapeutic gaps in SRHR

An R&D 'product gap' exists when there is an urgent need but low commercial incentive to engage in R&D for products to sufficiently treat, diagnose or prevent a disease or condition. Examples of product gaps for SRHR include human papilloma-virus (HPV) diagnostics and medicines for postpartum haemorrhage.

A Policy Cures Research report on R&D for SRHR identified several product gaps specific to LMICs for SRHR conditions and health needs through an in-depth consultation with an expert advisory group.⁴ Eleven SRHR diseases or health needs in scope have R&D product gaps; HPV-related cervical cancer, hypertensive disorders of pregnancy (pre-eclampsia), maternal haemorrhage (postpartum haemorrhage), STIs (particularly hepatitis B, herpes simplex virus type 2 (HSV-2), chlamydia, gonorrhoea, syphilis, human T-cell lymphotropic virus type 1 (HTLV-1) and HIV/AIDS),

Other is defined as projects which follow a different development cycle than R&D projects which target the treatment of a disease, such as a technical lifecycle for devices.

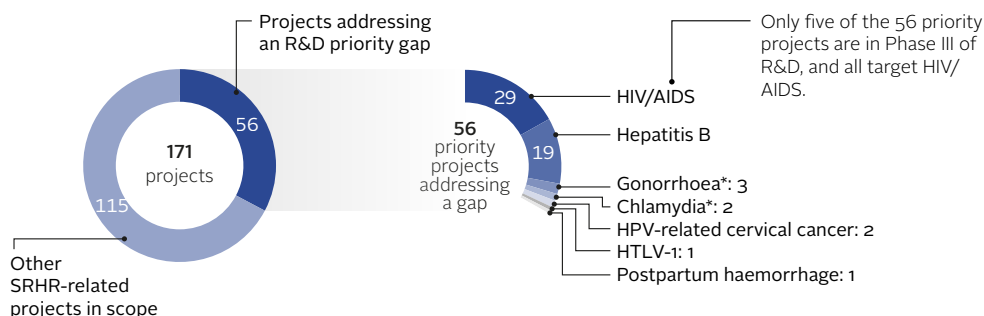
and contraceptives. The Index defines R&D projects in the pipeline that address product gaps as 'priority projects.'

Of the 171 SRHR-related projects in the R&D pipeline, 56 are projects in development that address product gaps for a priority disease (see Appendix I). The remaining R&D projects address other SRHR diseases in scope such as ovarian cancer.

To ensure the necessary therapeutics can be developed and ultimately reach more women and girls, more companies need to invest in R&D for SRHR-related diseases and health needs. Currently, only eight of the 20 companies included in the Index are conducting R&D for gaps in any of these therapeutic areas. These companies are AbbVie, Daiichi Sankyo, Gilead, GSK, Johnson & Johnson, MSD, Roche and Sanofi.

FIGURE 18 Almost all SRHR priority projects in the pipeline are directed towards HIV/AIDS and hepatitis B, while many other diseases remain unaddressed

There are 56 priority projects in the pipeline targeting at least one R&D gap covering six different SRHR-related priority diseases or health needs. There are no projects that address HSV-2, pre-eclampsia and syphilis, although they are diseases or health needs with R&D product gaps.



Missing R&D for products targeting STIs and HPV-related cervical cancer

Research is currently underway to address certain gaps (e.g., a preventative chlamydia vaccine), however, many gaps are unaddressed – such as therapeutic vaccines and medicines for HPV-related cervical cancer. Although HIV/AIDS and hepatitis B comprise 30% of all SRHR projects in the pipeline, there are no projects in development to address two of the identified product gaps – namely, microbicides for HIV and diagnostics for hepatitis B. There are also no R&D projects currently in development targeting product gaps for HSV-2 (commonly referred to as genital herpes), due to the termination of a project to develop a preventative vaccine for the virus.

Addressing specific R&D gaps for maternal health could reduce mortality in LMICs

Maternal mortality rates are disproportionately high in low-income countries, with an average of 462 deaths per 100,000 live births, compared with an average of 11 deaths per 100,000 in high-income countries.⁸ Several factors influence this, including distance to hospitals, inadequate healthcare services and a lack of access to existing medicines.

While addressing health system barriers is an important step in addressing high maternal mortality, R&D investment is also a key element that can help in this regard. One key gap in R&D for maternal health is for diagnostics for pre-eclampsia. None of the companies in scope have priority projects addressing this gap. An accurate diagnostic suitable for use in LMICs could lead to earlier detection and appropriate

*There is one diagnostic project in the pipeline targeting both chlamydia and gonorrhoea.

management of the condition, including timely referral, reducing rates of mortality.

Another notable R&D product gap is for products to treat postpartum haemorrhage, the leading cause of maternal deaths. Currently, treatment for this condition requires intravenous or intramuscular administration of oxytocin by a skilled health-care worker.⁴ A new formulation is needed that is both heat stable and can be easily and quickly administered as an alternative. Currently, among the companies in scope, there are no projects in development to address this need. However, through Merck for Mothers, MSD collaborated with Ferring Pharmaceuticals and WHO to support the advancement of Ferring's proprietary and investigational heat-stable carbetocin, for the prevention of postpartum haemorrhage. It's well-suited to use in LMICs as it can be stored and transported at much higher temperatures than oxytocin, and it was added to the 21st WHO Model List of Essential Medicines. It addresses part of the gap with its heat stability, but still needs to be administered intramuscularly. While a step in the right direction, companies can take further steps to address gaps in ease of administration.

Spotlight on clinical research during pregnancy

Pregnant and lactating women have been historically excluded from clinical trials for non-obstetric conditions, with safety concerns, ethical and legal considerations cited as reasons for their exclusion.⁹ As a result, the body of evidence to support clinical decision-making for medicines used during pregnancy is lacking, despite many women still needing and using medically necessary medicines throughout the course of their pregnancy.¹⁰ The underrepresentation of pregnant women in clinical trials means that the mechanism by which physiological changes in pregnancy alter the absorption and metabolism of medicines is poorly understood.¹¹

In 2021, the World Health Organization (WHO), alongside the International Maternal Paediatric Adolescent AIDS Clinical Trials Network (IMPAACT) and the International AIDS Society, issued a call to action to accelerate the study of new medicines for HIV in pregnant and breastfeeding women.¹² The report makes several recommendations for how the pharmaceutical industry can play its part to close the knowledge gap created by the exclusion of pregnant women from clinical research.

PRODUCT DELIVERY

Registration of many products in LMICs is lacking, but positive exceptions for essential HIV/AIDS medicines and contraceptives

The Index looks at how companies are utilising mechanisms such as registration and pricing strategies to improve access to their products in LMICs.

Despite standout examples, many SRHR-related products are not widely filed for registration in LMICs

Filing for registration with a national regulatory authority is the first step required to gain 'approval' before a product is launched on the market. Despite a high disease burden and unmet healthcare needs for SRHR-related products in LMICs, some products may never receive regulatory approval in countries in scope. When a product is not registered in a country, it limits choice and potentially leaves women and girls without essential and life-saving SRHR products.

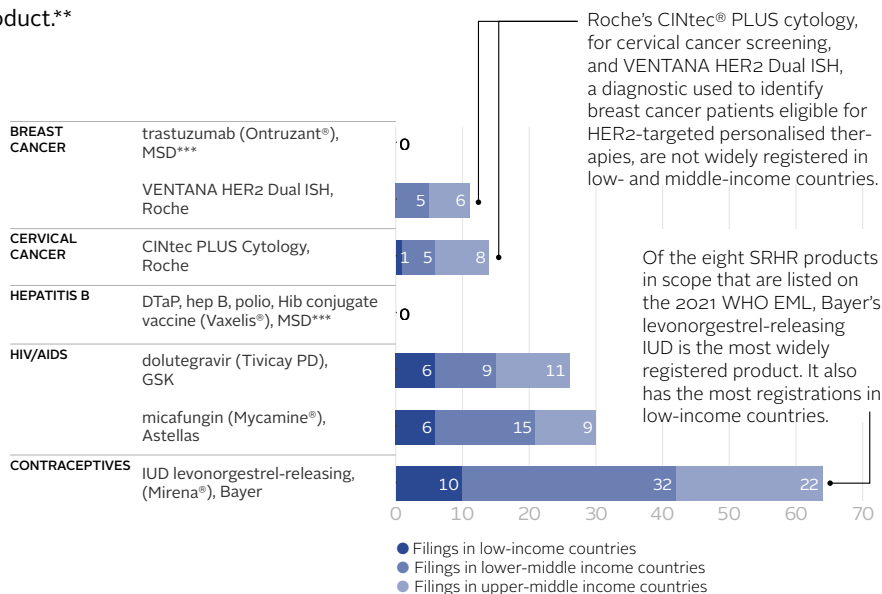
Of the 190 products analysed in the Index in terms of registration data, 39 were for SRHR-related diseases and health needs.* In general, older products like Bayer's levonorgestrel-releasing intrauterine system (Mirena®), which received its first global regulatory approval in 1990, are most widely registered in LMICs. The levonorgestrel-releasing intrauterine system is a form of long-term contraception, and is the most filed product within the SRHR-related scope of the Index, with a total of 64 filings in LMICs.

Although more recently-launched products are less widely registered across LMICs, some examples of good practice are seen. For example, trastuzumab/hyaluronidase-oysk (Herceptin Hylecta™) from Roche, approved by the US FDA in 2019, has been filed for registration in 58 countries within the scope of the Index.

Data analysed by the Index on which products have been registered, and where, suggests that – of the countries in scope – companies are most likely to register their products in middle-income countries. Only 18 (46%) out of the 39 products have been filed for registration in any low-income countries. For example, Uganda has 11 products filed, while Mozambique has 5 and both Ethiopia and Rwanda have 4. Although several barriers may make registration in some countries more challenging, companies should now ensure more SRHR products are filed consistently across low-income countries, with a particular focus on the countries with a high burden of the disease targeted by their particular product.**

FIGURE 19 Number of registration filings in LMICs for SRHR-related products defined as “essential” by the World Health Organization

Among the products in scope of this analysis, eight are on the WHO Model List of Essential Medicines (EML), which is a list of the medicines considered to be most effective and safe to meet the most important needs in a health system. The companies have marketing rights for seven of these products. This figure shows the number of the 108 LMICs in which these products are filed for registration, broken down by whether the filing is in a low-, lower-middle or upper-middle income country.



*A maximum of ten recently-launched products were included in the Index for analysis of product registration. As some newer products are not indicated for SRHR-related diseases and health needs, information is not available for all 176 products in scope of this special report. For Eli

Lilly and MSD the exact registration status of their latest products within LMICs could not be reported as no data was provided/verified or available in the public domain during the period of analysis.
 **High disease burden countries are those that are among the ten countries with

the highest disability-adjusted life year (DALY) value, for any particular disease. One DALY equals one lost year of healthy life, allowing for an estimation of the total number of years lost due to specific causes (e.g., diseases and injuries).

***No data about filings for Ontruzant® and Vaxelis® was submitted by MSD, and no evidence was found in the public domain. DTaP: Diphtheria, tetanus pertussis (acellular, component); hep B: hepatitis B; polio: poliomyelitis; Hib: Haemophilus type b.

Recent steps forward on registering HIV/AIDS products where the need is greatest, but mixed picture overall

Some companies have performed well on registering their HIV/AIDS products in countries with a high burden of the disease, but some key products are not registered in the countries where the need is greatest. The ten countries with the highest burden of HIV/AIDS (among adults) are Lesotho, Eswatini, Mozambique, South Africa, Botswana, Equatorial Guinea, Namibia, Zimbabwe, Zambia, and the Central African Republic.

Both emtricitabine/tenofovir alafenamide (Descovy®) from Gilead and dolutegravir (Tivicay PD) from GSK (via its majority-owned business specialising in HIV products, ViiV Healthcare), have recently been filed for registration in seven high disease burden countries. Specifically, dolutegravir has been filed for registration in these countries within two years of being approved by the US FDA.

However, for the remaining HIV/AIDS products in scope, five have all been filed in less than three of the ten countries with the highest burden of disease, while the remaining eight products have not been filed in any of these ten countries.

PRODUCT DELIVERY

What are companies doing to ensure their SRHR products are available and affordable?

Access strategies are ways in which companies can make sure their products reach the people who need them. Companies should put strategies in place for their products to increase availability, affordability and supply in LMICs, ensuring these strategies are tailored for both the product and the country.

Products in scope of this analysis

This Special Report analyses access strategies for 44 products indicated for SRHR-related diseases and health needs, looking at the products that have been sampled from companies' portfolios according to the Index methodology. All the companies in scope have at least one product included in this analysis, with the exception of Boehringer Ingelheim, Merck and Novo Nordisk. Of these products, 17 are analysed as supranationally-procured products. The other 27 are analysed in terms of companies' strategies to ensure access to the product to individual countries.

What is pooled procurement and which companies participate?

Supranational procurement agreements are pooled procurement mechanisms whereby large volumes of health products are purchased by an organisation for supply in multiple countries. This is an important mechanism to ensure a sufficient supply of affordable SRHR-related products are available in LMICs, especially the poorest countries.

Eight of the companies in scope – AbbVie, Bayer, Bristol Myers Squibb, Pfizer, GSK, MSD, Roche and Johnson & Johnson – engage in international agreements for the procurement of SRHR products. Between them, they work with organisations including Gavi, the Vaccine Alliance (Gavi); the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund); UNITAID; Clinton Health Access Initiative (CHAI); and the Pan American Health Organization (PAHO).

Supranational procurement of HPV vaccines to prevent cervical cancer

In 2020, an estimated 90% of global deaths from cervical cancer occurred in LMICs,¹³ where access to preventative products such as the HPV vaccine are limited. In an effort to reduce the number of women dying from this preventable disease, 41 countries in scope have introduced national HPV immunisation programmes. Two companies in scope (GSK and MSD) supply HPV vaccines to countries in scope of the Index through Gavi's pooled procurement mechanism. Programmes such as Gavi's play an important part in reducing deaths from cervical cancer.

It is important that companies consider the access needs of people living in countries that do not qualify for Gavi support. For example, due to the high cost of the vaccine, non-eligible countries may face challenges in budgeting for vaccination programmes. In recognition of this, both GSK and MSD have agreed, with conditions and for a limited timeframe, to continue to support countries that have transitioned from Gavi by providing HPV bivalent vaccine (Cervarix®) and HPV quadrivalent vaccine (Gardasil®), respectively, at the same price they were accessed when supported by Gavi.

GOOD PRACTICE

GSK's supranational procurement strategy for its HPV vaccine

GSK's HPV bivalent vaccine is supplied through supranational agreement via Gavi. GSK applies tiered pricing for this product, based on World Bank income classifications (whether a country is high-, upper-middle, lower-middle or low-income), with countries eligible for Gavi's programme eligible for the lowest price for the vaccine.

GSK has also committed to applying the same terms of the agreement to countries that have transitioned out of the Gavi programme (e.g., if they have moved into a different income classification) and therefore don't receive the lowest cost for vaccines. GSK also applies an equitable pricing strategy in South Africa, a country not eligible for Gavi support, by offering its HPV bivalent vaccine to the Ministry of Health via a tender process. Since South Africa's HPV immunisation programme began in 2014, GSK has won all tenders based on the cost of vaccines.

Access to contraceptives through supranational procurement and pricing strategies

In 2019, it was estimated that of the 1.1 billion women of reproductive age that have a need for family planning, 270 million still had an unmet need for contraception.¹⁴ Access to contraception is important to prevent unwanted pregnancy and pregnancy-related health risks for women living in LMICs. Pregnancy-related health risks disproportionately impact women in LMICs, where an estimated 94% of maternal deaths occurred in 2017.¹⁵

Global access to contraception is increasing, with the United Nations Population Fund (UNFPA), the world's largest supranational procurer of contraceptives, reporting that an additional 60 million women and girls were using modern contraceptives in 2020 compared to 2012 via its supranational agreements and public-private partnerships.

GOOD PRACTICE

Bayer's participation in supranational procurement for Jadelle®

Bayer is the biggest supplier of contraceptives to UNFPA, accounting for 11% of UNFPA procurement in 2021.¹⁶ Bayer supplies its levonorgestrel-releasing implant (Jadelle®), a long-acting reversible contraceptive (LARC) that provides contraception for up to five years. Within the last ten years the annual volume of the levonorgestrel-releasing implant has quadrupled and in total more than 49 million implants have been provided to the world's poorest countries. This is important as LARCs, including implants, can be a safe and cost-effective alternative to short-acting contraceptives.

GOOD PRACTICE

Pfizer's participation in supranational procurement for Sayana Press®

Pfizer supplies subcutaneous depo medroxyprogesterone acetate (Sayana Press®), a LARC providing at least 13 weeks of contraception, through Family Planning 2030 (FP2030). Subcutaneous depo medroxyprogesterone acetate has several characteristics that make it well suited for low-income countries, particularly its potential for self-administration, its length of contraceptive cover, compact and discreet size, and shelf life at room temperature.

Although supranational procurement agreements are important means of providing access in the world's poorest countries, these agreements are often limited to a small group of products for women's health conditions – particularly contraceptives, HIV/AIDS medicines and diagnostics and HPV vaccinations.

NCDs, such as breast and uterine cancer, have so far not been included in supranational procurement agreements. Therefore, to ensure access in LMICs, companies should particularly pursue access strategies – outside of supranational agreements – to ensure their NCD products reach these countries.

Examining access strategies and equitable pricing for SRHR-related products

It is important that companies tailor access strategies to overcome barriers to access that are specific to the country. This means considering challenges presented by weak health and regulatory systems in LMICs. A good access strategy has equitable pricing that considers the ability to pay of different buyers (both public and private) in all contexts (between upper-middle, lower-middle and low-income countries, and also between countries) and additional non-pricing initiatives to maximise the reach of low-income patients.

Lack of access strategies for oncology products, especially in low-income countries

Although the quality of access strategies varies across products and countries, the Index found that in low-income countries, companies consistently do not have access strategies in place for some SRHR products. Weak health systems, lack of regulatory capacity and inadequate funding pose challenges to reaching patients in low-income countries.

This gap in access is particularly pronounced for oncology products, especially breast cancer. The Index analysed access strategies for 14 breast cancer products, of these 11 (78%) did not have an access strategy in any low-income country in scope. Products for HIV/AIDS and hepatitis B are more likely to be covered by access strategies in low-income countries. Of the combined total of six products for these indications that are included in this analysis, five products had an access strategy in at least one low-income country.

Companies could consider non-exclusive voluntary licensing for key breast cancer products

Despite the complexities in accessing markets in low-income countries, companies can think beyond traditional routes to provide access to these patients. One mechanism to achieve this is non-exclusive voluntary licensing, where, under certain terms and conditions, the company agrees to allow sub-licensees to manufacture and sell generic versions of their products in LMICs. Currently, the only non-exclusive voluntary licences addressing the SRHR diseases in scope of this report are for HIV.

The Medicines Patent Pool (MPP) is an intermediary that facilitates licensing agreements between pharmaceutical companies and generic manufacturers, and it has identified three products to treat breast cancer. Where gaps in access for these products exist, voluntary licensing through MPP would lead to substantial public health impact. The products identified include ribociclib (Kisqali®) from Novartis, abemaciclib (Verzenio®) from Eli Lilly and palbociclib (Ibrance®) from Pfizer.

GOOD PRACTICE

Novartis's access strategies for its maternal haemorrhage product

For its product methylergonovine maleate, for maternal haemorrhage, Novartis can demonstrate examples of good access strategies in at least one upper-middle income country (Colombia), a lower-middle income country (India) and a low-income country (Togo).

Although the strategies implemented in Colombia and India are more comprehensive, Novartis does report some efforts to improve affordability in Togo.

In Colombia, the product is included in the national Health Benefit Plan and is offered to patients at no cost. Novartis's price is based on budget impact and prices in external reference countries. In India, in addition to pricing strategies, Novartis manufactures locally and has eliminated promotional investments to decrease cost to the patient.

Togo's national health authority is responsible for setting the price of methylergonovine maleate (Methergine®), and patients pay out of pocket in the private channel. Novartis reports that during price negotiations with the government, local affordability was considered.

Methylergonovine is also included in the list of essential medicines.

PRODUCT DELIVERY

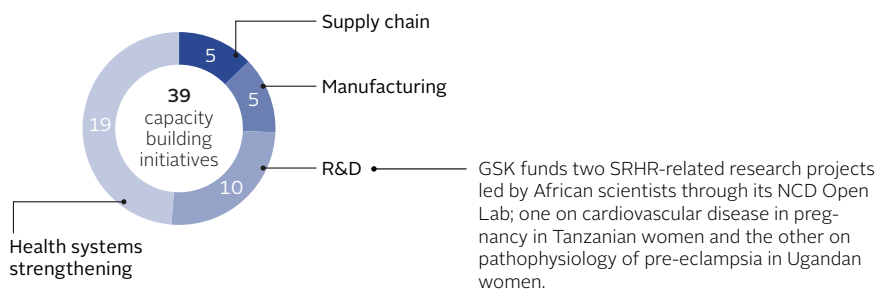
What are companies doing to ensure the uptake of SRHR products and care in LMIC health systems?

In addition to developing and researching new products, capacity building is another way companies can help improve access to medicine and address issues in the availability and accessibility of SRHR products. Health systems, supply chains, and manufacturing capacity within LMICs should be equipped for delivering SRHR treatments to women and girls. Companies can also build R&D capacity in LMICs to develop medicines and vaccines for SRHR-related products.

What kinds of capacity building initiatives are companies involved in for SRHR?

FIGURE 20 Engagement in capacity building for SRHR varies across fields

While companies are engaged in multiple health systems strengthening initiatives for SRHR, fewer examples are seen for supply, manufacturing or R&D capacity building initiatives.



Health systems strengthening to address uptake of SRHR products

Of the capacity building efforts assessed in the Index, health systems strengthening initiatives are the most common way that companies address SRHR-related diseases and health needs, with 11 companies involved in a combined total of 19 initiatives. Through initiatives like MSD for Mothers, Takeda and World Vision's Healthy Village programme, or Roche's involvement with NJIA, companies are addressing health system gaps, such as lack of trained healthcare workers and lack of disease awareness.

MSD for Mothers began in 2011 and has the largest country reach out of all the SRHR-related capacity building initiatives seen in the Index, targeting 31 LMICs in scope of the Index. It is a USD 650 million global initiative that contributes the company's scientific and business expertise and financial resources to address preventable maternal deaths through supporting quality maternity care and access to modern contraception. MSD has worked with more than 150 collaborators and has reached over 18.2 million women globally through its programmes that aim to support safe, high-quality and respectful maternal care.

Notably, 11 of the 19 health systems strengthening initiatives for SRHR are active in a single country. Especially when outcome measurements show impact like reduced maternal mortality or improved patient awareness, companies can now act to scale up their health systems strengthening efforts to reach more women and girls in countries with high disease burden or unmet health needs.

Companies can help address supply chain barriers through capacity building

Fewer examples are seen of companies engaging in supply chain capacity building, despite supply being a major barrier to accessing SRHR products. Although several supply barriers require efforts from governments and other local stakeholders, some companies are performing well in capacity building, by supporting efforts from local and international actors.

Supply chain issues like a lack of trained staff and weak information systems pose a threat to the continuous supply of contraceptives in LMICs. Several agencies

like UNFPA are actively working in LMICs and low-income countries to support supply of contraceptives in addition to other SRHR products. However, such agencies rely on partnerships with pharmaceutical companies, who supply the necessary products and greatly impact product availability, affordability, and uninterrupted supply. Four companies engaged in supply chain capacity building specifically targeting SRHR-related diseases and health needs, three of which report working directly with the UNFPA. For example, Bayer is one of the three suppliers of implants and oral contraceptives for the Reproductive Health Supplies Coalition's (RHSC), Global Family Planning Visibility and Analytics Network (GFP-VAN) and participated in shaping the platform. As of April 2022, the RHSC reported that its efforts to mitigate stockouts averted 2 million pregnancies across 48 countries and provided 373,000 additional CYPs* across 37 countries.

Reaching women and girls through inclusive business models

Inclusive business models are scalable, commercially viable models that provide goods, services and livelihood opportunities to low-income populations. These models are particularly relevant for women and girls, as they are disproportionately impacted by poverty and face additional barriers to access. Several constraints prevent companies from including women and girls as consumers, employees or producers in their value chain, such as gender-based expectations, limited literacy, and lack of rights and agency. Nonetheless, if pharmaceutical companies want to ensure that the entire income pyramid is able to benefit from accessing their medicines, they must engage in inclusive business models that target these groups.

Nine of the twenty companies in scope of the Index show evidence of their engagement in inclusive business models that address SRHR-related diseases and health needs (AstraZeneca, Bayer, Boehringer Ingelheim, Gilead, Johnson & Johnson, MSD, Novartis, Pfizer and Roche), despite 19 companies having products in their portfolio that cover SRHR diseases or health needs. Although half of the SRHR inclusive business models evaluated target maternal health, women's health needs extend beyond those related to reproduction. Across all disease areas, companies can address women and girls' unmet access needs using inclusive business models.

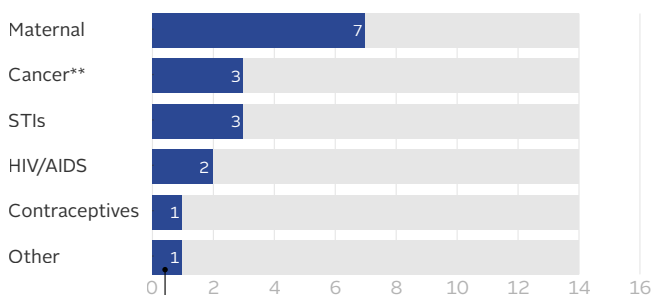
GOOD PRACTICE

In the Philippines, Novartis has an inclusive business model for its breast cancer treatment

In 2021, Novartis launched an inclusive business model to help low-income women in the Philippines access and afford ribociclib (Kryxana®/Kisqali®) for breast cancer treatment. Through research, the company found that patients in the Philippines began treatment but were unable to sustain treatment due to the cost. The company subsequently launched a model where patients pay less for a longer duration of treatment, thus incentivising adherence. Further, to enable implementation of a progressive discounting scheme across different pharmacy partners, Novartis partnered with a technology provider to extend eligibility of patients to the scheme and assist them in areas such as enrolment, eligibility tracking and medicine compliance reminders. In parallel, Novartis is also working with governments to encourage inclusion of ribociclib in the national formulary to support government reimbursement for the product for those that require it.

FIGURE 21 **Inclusive business models cover multiple SRHR-related disease areas and health needs**

Half of the SRHR-related inclusive business models analysed by the Index are targeted toward addressing maternal health needs.



One of the business models covered by this analysis includes women as employees in the company's value chain, but does not cover a specific disease area.

*The United States Agency for International Development (USAID) defines Couple-Years of Protection (CYP) as the estimated protection provided by family planning methods during a one-year period, based upon the volume of all

contraceptives sold or distributed free of charge to clients during that period. This includes permanent methods, such as sterilisation, and the lactational amenorrhea method.

**Cervical and breast cancer

NEXT STEPS

What can companies do to ensure women and girls in LMICs have access to the SRHR-related products they need?

R&D investment and clinical trials

Of the SRHR-related diseases and health needs included in this report, cancers, hepatitis B and HIV/AIDS draw the bulk of the R&D focus. The remaining half of the diseases and health needs make up less than 10% of the SRHR pipeline, with some not addressed at all. More R&D investment in these areas is needed, especially to fill product gaps for diseases and health needs that currently remain unaddressed, for example, pre-eclampsia and postpartum haemorrhage. Furthermore, there is an underrepresentation of pregnant women in clinical trials and, where appropriate, companies can make additional efforts to include them in clinical research in line with WHO recommendations.

Supporting access through supranational procurement

Companies' efforts to make their products affordable in LMICs are unbalanced, with areas for improvement, especially in access to SRHR-related non-communicable diseases. Pooled procurement via supranational agreements is focused on HIV medicines and diagnostics, HPV vaccines, and contraceptives. When countries are not eligible, or no longer eligible (due to their income classification changing) to benefit from supranational procurement, companies should develop access strategies for these countries to ensure that women and girls can access medicines at a similar price.

Access strategies for more products, in more countries

For key products in their portfolios, and particularly for non-communicable diseases like ovarian cancer, endometriosis and uterine cancer, for which there is no supranational procurement mechanism, companies must implement country-specific access strategies to ensure equitable access. Access strategies are generally missing in low-income countries, especially for breast cancer, while treatments for HIV/AIDS and hepatitis B are mostly covered by equitable pricing strategies across all income tiers. Companies can take steps to develop access strategies for these products and ensure that they reach women and girls living in low-income countries.

Investment in capacity building and tailoring inclusive business models

Companies have an additional role to play beyond researching and supplying products. Barriers such as lack of awareness, supply chain barriers, and lack of trained health workers also need to be addressed. Higher levels of company engagement in health systems strengthening are needed and efforts can be made to scale up these initiatives to more countries where there are women and girls with unmet access needs. Companies can engage with partners, such as the UNFPA, to build supply chain capacity for SRHR products in specific areas including demand forecasting and improving infrastructure for storage and delivery of medicines.

In addition, several companies have SRHR products in their portfolio, like contraceptives, products indicated for HIV/AIDS, and cancer therapies, that are only accessible through regular business practices that may not be inclusive, meaning that they are not tailored to address the specific needs of women and girls.

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