

Improving maternal health and access to contraceptives: pharmaceutical companies' contribution to MDG 5

Landscape Study

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Pharmaceutical companies operationalise commitments to MDG 5 with a variety of initiatives

Ten of the world's largest pharmaceutical companies are taking some action to improve access to maternal health and family planning, by making public commitments and/or implementing a range of initiatives. This includes five out of six companies with relevant products. All initiatives involve partners and the majority focus on local capacity building.

With the Sustainable Development Goals due to be launched this year, this report can be used as a baseline for monitoring whether and how individual research-based pharmaceutical companies are working to improve access to maternal and reproductive health. Measuring progress against such targets is key for maintaining momentum and focus.

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This landscape study analyses data submitted by pharmaceutical companies for the 2014 Access to Medicine Index, supplemented by additional desk research. The Access to Medicine Index is published by the Access to Medicine Foundation, a non-profit organisation based in the Netherlands that aims to advance access to medicine by encouraging the pharmaceutical industry to play a greater role in improving access to medicine in less developed countries. The Index methodology was developed, and is continually refined, in consultation with multiple stakeholders including the World Health Organization, NGOs, governments, universities and institutional investors. The Index is funded by the Bill & Melinda Gates Foundation, the Dutch Ministry of Foreign Affairs and the UK Department for International Development.

Executive Summary

Pharmaceutical companies operationalise commitments to maternal and reproductive health with a variety of initiatives

Every day, an estimated 800 women die from preventable causes related to pregnancy and childbirth. Governments, multi-lateral organisations and civil society have long been calling for action to improve this situation, most notably through the Millennium Develop Goals (MDGs). MDG 5 sets targets toward reducing the maternal mortality ratio and achieving universal access to reproductive health-care. Measuring progress against these targets is key for maintaining momentum as we transition toward the Sustainable Development Goals (SDGs).

This is the first landscape study to assess whether and how pharmaceutical companies are responding to international calls for action on maternal and reproductive health. It finds evidence that companies are taking some action here, by making public commitments and implementing a range of initiatives.

The potential role for pharmaceutical companies in this area centres on a few key health priorities, particularly R&D gaps that relate to the specific needs of women living in developing countries. Research-based pharmaceutical companies have the knowledge and technical expertise needed to adapt and improve those product characteristics that create access barriers in developing countries. For example, the development of heat-stable oxytocin for preventing excessive bleeding during childbirth would reduce the need for complex cold-chains.

Table 1: Overview of companies with on-market products and/or initiatives for maternal and reproductive health.

	Maternal Health					Family Planning	Women's Health	NCDs
	General maternal health	Maternal sepsis	Maternal haemorrhage	Obstructed labour	Hypertensive disorders of pregnancy			
Astellas	■						■	
Bayer						■ ■		
Daiichi Sankyo	■							
GSK	■		■					
Johnson & Johnson	■					■	■	
Merck & Co.	■	■ ■	■			■ ■		
Novartis	■	■	■	■	■			
Novo Nordisk								■
Pfizer	■	■				■ ■		
Roche		■			■			
Sanofi	■							

* There are no pharmaceutical products available for fistula. This analysis does not include products for the treatment of diabetes.

- The company has/ supports initiatives for this condition
- The company has products to treat this condition

Beyond R&D, pharmaceutical companies can contribute in other areas, not least with regard to ensuring the affordability and availability of products, and building local capabilities for providing healthcare.

To provide the first overview of pharmaceutical companies' activities in this area, this study analyses data submitted to the 2014 Access to Medicine Index by 20 of the world's largest research-based pharmaceutical companies. It finds that five of the six companies with relevant products on the market have made public commitments to address access to maternal and reproductive health; they have operationalised these commitments through a range of initiatives to increase access. Importantly, they are joined by a further five companies that are implementing access initiatives despite having no relevant products.

Findings

Five of the six companies with relevant products are making public commitments and taking some action, together with others

- **Products:** In total, six of the 20 companies analysed have products on the market that are relevant to maternal and reproductive health. Between them, they have 37 products, including a large proportion of contraceptive methods (18 in total, from four companies).
- **Commitments:** Seven companies have separately committed to advancing the UN's Global Strategy for Women's and Children's Health (aligned with MDG 5) by implementing activities to improve maternal and reproductive health. This includes five of the companies with relevant products.
- **Initiatives:** 10 companies are actively implementing initiatives for improving maternal health and/or access to family planning products. These 10 companies include the five that have both relevant products and have made commitments to action in this area.

Pharmaceutical companies are implementing a wide variety of relevant initiatives; all involve partners and the majority focus on local capacity building

- There are 28 relevant initiatives that aim to improve maternal health and access to family planning products in developing countries. All involve partnerships with international organisations, NGOs, governments, private-sector partners, foundations, universities and/or non-profit organisations. Most are new since 2012 or have been recently expanded.
- The majority of initiatives have a strong focus on local capacity building (19 in total), including nine that concentrate on using digital technologies through e-learning platforms and/or mobile health applications.
- There are few R&D initiatives, which all target bleeding during childbirth (post-partum haemorrhage), which is the R&D gap with the highest priority. Significant other needs remain, including for new contraceptives and antibiotics.
- 25% of initiatives include action on pricing: seven initiatives, from five companies, mostly relating to contraceptives.
- 10 initiatives, from 5 companies, are aligned with the core business of the company in question, making them more likely to be sustainable longer term.

Looking ahead

Based on our analysis, there is a correlation between the companies that commit publically to improving access to maternal and reproductive health and those that also take action. It is particularly encouraging to see that companies without relevant products also support and implement initiatives aligned with the targets set in MDG 5. This supports our view that research-based pharmaceutical companies can contribute in the area of health systems strengthening.

Together with experienced and independent partners, pharmaceutical companies are encouraged to: 1) leverage relevant R&D expertise and know-how; 2) evaluate the impact of existing initiatives and their long-term sustainability; 3) expand existing commitments and activities in this area where deemed appropriate and effective; and 4) actively evaluate new methods for addressing the specific challenges set out in the forthcoming SDGs.

Action to improve maternal and reproductive health clearly starts with an international will to act from multiple parties, underpinned by a high degree of clarity regarding the appropriate role for each stakeholder, including pharmaceutical companies. The MDGs will conclude this year and be replaced by the SDGs. As stakeholders work toward achieving these new goals, rigorous monitoring and benchmarking will continue to be crucial for identifying what works in the long-term and what needs to be adapted. This report can be used as a baseline for monitoring whether and how individual research-based pharmaceutical companies are working to improve access to maternal and reproductive health.

Introduction

Every day, approximately 800 women die from preventable causes related to pregnancy and childbirth. In 2013 alone, about 289,000 women died due to complications arising during pregnancy and childbirth (WHO, 2014a). 99% of these deaths occur in developing countries, with more than half in sub-Saharan Africa and almost one third in Asia. Maternal mortality is highest in rural areas and among poor and less educated communities. Health conditions related to pregnancy and childbirth are the second cause of death (after HIV/AIDS) among women of reproductive age in developing countries (ibid). Among girls aged between 15 and 19, complications arising from pregnancy and childbirth are the leading cause of death (WHO, 2014b).

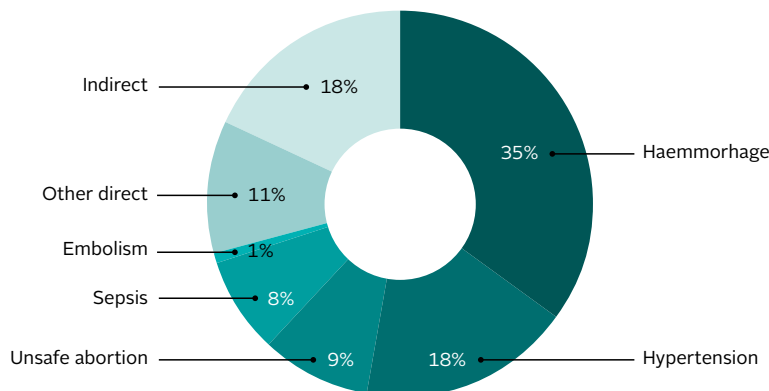
Improving maternal health has long been a global health priority (Say *et al.* 2014), as reflected in several declarations and global resolutions, most notably the Millennium Development Goals (MDGs): MDG 5 aims to improve maternal health by reducing the maternal mortality ratio by 75% between 1990 and 2015 and by achieving universal access to reproductive healthcare by 2015 (UN, 2014). By 2013, a reduction of 45% in the maternal mortality ratio had been achieved (from 380 deaths per 100,000 live births in 1990 to 210 deaths per 100,000 live births in 2013; WHO, 2014c). Although significant, this nevertheless falls short of the global goal. In order to accelerate progress, the UN Secretary-General launched the 'Global Strategy for Women's and Children's Health' in 2010.

UN Global Strategy for Women's and Children's Health

The UN Global Strategy sets out key areas where action is urgently needed in order to increase financing, to strengthen policy and improve service delivery (WHO, 2010). It calls on the global community to work together to save 16 million lives by 2015 through increasing access to and appropriate use of essential medicines, medical devices and health supplies that effectively address the leading, avoidable causes of death during pregnancy, childbirth and childhood (UN, 2012). This paper focuses specifically on actions taken by large, research-based pharmaceutical companies to improve maternal health and access to contraception.

The four leading causes of maternal deaths globally are (1) severe bleeding (post-partum haemorrhage), (2) infections (maternal sepsis), (3) unsafe abortion and (4) hypertensive disorders (pre-eclampsia and eclampsia) (see Figure 1). One study reports that, between 2003 and 2009, haemorrhage, sepsis and hypertensive disorders were responsible for more than half of all maternal deaths worldwide (Say *et al.*, 2014). It is important to note that most deaths caused by these four conditions can be prevented through skilled care at childbirth and access to emergency obstetric care. For example, in sub-Saharan Africa, where maternal mortality ratios are highest, less than 50% of women are attended to by a trained midwife, nurse or doctor during childbirth (WHO, 2014d). Scaling up access to maternal and reproductive health commodities would also have a significant impact on these statistics.

Figure 1: Global estimates of the causes of maternal deaths (1997 - 2007)



Source: WHO and UNICEF, 2012

The UN's *Global Strategy for Women's and Children's Health* is being put into action by the UN Commission on Life-Saving Commodities for Women and Children (part of the *Every Women, Every Child* movement, or EWEC¹). The Commission is working to achieve equitable access to 13 life-saving commodities (ibid), including three maternal and three reproductive health commodities. It is estimated that scaling up access to the three maternal health commodities would save 70,000 lives over a five-year period; and that increased access to and use of the three reproductive health commodities would avoid 230,000 maternal deaths per five-year period. It is estimated that an investment of US\$2.6 billion over five years to increase access to all 13 life-saving commodities specified in the UN's *Global Strategy* would save approximately 6 million lives.

Access to family planning

Expanding access to family planning is generally regarded as an effective strategy for saving women's and children's lives and improving their health. It is estimated that 222 million women in developing countries want to delay pregnancy or prevent unintended pregnancies but are not using modern contraception methods (International Conference on Family Planning, 2013). Unmet needs for contraception result in 54 million unintended pregnancies and 16 million unsafe abortions, resulting in 79,000 maternal deaths (ibid). Family planning reduces maternal deaths due to these unsafe abortions, and, as 40% of all pregnancies worldwide are unintended, family planning products can help to break the cycle. Furthermore, spacing pregnancies at least two years apart and limiting the total number of pregnancies improves survival chances and health for both mothers and children (WHO and UNICEF, 2012).

In order to support the right of women and girls to decide freely and for themselves whether, when and how many children they want to have, Family Planning 2020 (FP2020) was launched. It was one outcome of the 2012 London Summit on Family Planning, which called for unprecedented global political commitments and resources to enable 120 million more women and girls in the world's 69 poorest countries to use contraceptives by 2020. It is a global partnership working with governments, civil society, multi-lateral organisations, donors, the private sector and the research and development community (FP2020, 2015).

Table 2 provides an overview of the three maternal health commodities and three reproductive health commodities included in the UN's *Global Strategy to improve Women's and Children's Health*, as well as examples of key related access barriers, and the commodities' potential 5-year impact should access be improved.

Table 2: Estimation of lives saved should common barriers be overcome and equitable access achieved for six life-saving commodities for maternal and reproductive health.

Commodity by life stage	Condition	Examples of key barriers	Potential 5-year impact
Maternal Health Commodities			
<i>Oxytocin</i>	Post-partum haemorrhage	Often poor quality, drug shortages	15,000 maternal lives saved
<i>Misoprostol</i>	Post-partum haemorrhage	Not included in national essential medicines list	
<i>Magnesium sulphate</i>	Eclampsia and severe pre-eclampsia	Lack of demand by health workers	55,000 maternal lives saved
Reproductive Health Commodities			
<i>Female condom</i>	Family planning/ contraception	Low awareness among women and health workers	Almost 230,000 maternal deaths averted
<i>Contraceptive implants</i>	Family planning/ contraception	High cost	
<i>Emergency contraception</i>	Family planning/ contraception	Low awareness among women	

Source: adapted from UN Commission on Life-Saving Commodities for Women and Children – Commissioner's Report (UN, 2012).

Role of the Pharmaceutical Industry

In order to reach the MDG targets related to maternal and reproductive health, support and collaboration is needed from various stakeholders, such as governments, multilateral organisations, civil society and the private sector. The *UN Global Strategy for Women's and Children's Health* (UN, 2012) calls upon pharmaceutical companies to:

- Scale up best practices and partner with the public sector to improve service delivery and infrastructure;
- Develop affordable new drugs, technologies and interventions;
- Invest additional resources, provide financial support, ensure quality and reduce prices for goods; and
- Ensure community outreach and mobilization, coordinated with health-care workers.

It is argued that pharmaceutical companies can “benefit their own balance sheets and reputations while also addressing social issues” by “creating ‘shared value’” (PMNCH, 2012): by 1) reconceiving products and markets; 2) reconfiguring value chains and 3) by strengthening local clusters. It should be noted that individual companies rarely have the legitimacy, expertise and resources to act alone: cross-sector, cross-industry partnerships are a key success factor (PMNCH, 2012). However, despite the global community's call for action, no collective private-sector effort has yet arisen in this area.

Specific R&D gaps exist

The role for pharmaceutical companies in this area is focused on a few key needs, particularly with regard to addressing specific R&D gaps for maternal health conditions and contraceptive methods that are suitable for use in developing

countries (Policy Cures, 2015). Pharmaceutical companies have the know-how and technical expertise needed to address, through R&D, product characteristics that create barriers for access in developing countries: such as heat-sensitivity and administration routes that require healthcare professionals. This would include, for example, the development of heat-stable oxytocin and simple, effective contraceptives. Many R&D projects that target developing country needs are conducted in collaboration with publically funded R&D partners, such as PATH. An overview of pharmaceutical R&D needs is presented in Table 3.

Table 3: Pharmaceutical R&D needs for maternal health conditions and family planning

	Product	R&D need	Source
Maternal Health Conditions			
Maternal Sepsis	Antibiotics	<ul style="list-style-type: none"> • New and adapted antibiotics due to resistant organisms 	<ul style="list-style-type: none"> • Oxfam, 2008
Post-partum haemorrhage	Oxytocin (treatment)	<ul style="list-style-type: none"> • Thermo-stable oxytocin formulation • Non-parenteral inhalation/intranasal spray-dried (dry powder) 	<ul style="list-style-type: none"> • UN, 2012 • Policy Cures, 2015
	Misoprostol (prevention)	<ul style="list-style-type: none"> • Efficacy and potential side effects 	<ul style="list-style-type: none"> • Policy Cures, 2015
	Oxytocin analogues	<ul style="list-style-type: none"> • Thermo-stable formulations 	<ul style="list-style-type: none"> • Policy Cures, 2015
	Blood-clotting drugs	<ul style="list-style-type: none"> • Blood-clotting drugs that specifically affect uterine bleeding 	<ul style="list-style-type: none"> • Policy Cures, 2015
Hypertensive disorders of pregnancy	Magnesium sulphate	<ul style="list-style-type: none"> • Simplified dosing regimen and single dose packaging • Spring-driven infuser pump or other drug-administration device 	<ul style="list-style-type: none"> • UN, 2012
Family Planning			
Contraceptive methods	Oral contraceptives	<ul style="list-style-type: none"> • Contraceptives that are usable on demand • Contraceptives that are safe to use while breast-feeding • Non-hormonal contraceptives 	<ul style="list-style-type: none"> • Policy Cures, 2015 • Darroch, Sedgh and Ball, 2011 • DSW, 2014
	Contraceptive implants	<ul style="list-style-type: none"> • New, long-acting reversible contraceptives (e.g., biodegradable contraceptive implant) • Non-hormonal contraceptives 	<ul style="list-style-type: none"> • Policy Cures, 2015
	Injectable contraceptives	<ul style="list-style-type: none"> • New, long-acting reversible contraceptives 	<ul style="list-style-type: none"> • Policy Cures, 2015
	Intra-uterine devices	<ul style="list-style-type: none"> • New, long-acting reversible contraceptives • Non-hormonal IUDs 	<ul style="list-style-type: none"> • Policy Cures, 2015 • Darroch, Sedgh and Ball, 2011
	Other contraceptive methods	<ul style="list-style-type: none"> • New, long-acting reversible contraceptives (e.g., injectable contraceptives) • Thermo-stable products (e.g., contraceptive rings) • Non-surgical permanent contraception 	<ul style="list-style-type: none"> • Policy Cures, 2015

Maternal health conditions have not traditionally attracted high R&D investments from the pharmaceutical industry and other players. A recent report shows that R&D spending on reproductive and maternal health issues in developing countries received US\$88 million in 2013, versus US\$3.2 billion in R&D spending on neglected diseases, including malaria and tuberculosis (Policy Cures, 2015). Underinvestment by the pharmaceutical industry has been matched by underinvestment from the public sector (Fisk, McKee and Atun, 2011). This same study finds that, in high-income countries, only 1–3% of health research expenditure was on maternal and perinatal health. In low-income settings, government funders focus mainly on infectious diseases despite the high disease burden in these countries (ibid).

It is argued that push (e.g., fast track FDA approvals; the GAVI Alliance) and pull mechanisms (e.g., advanced market commitments; PEPFAR) related to MDG Target 8^{e11} have not been effective for improving maternal health (Fisk and Atun, 2008). These mechanisms have focused predominantly on vaccines and neglected tropical diseases, with limited focus on maternal health. There are several reasons for this market failure, including: a reluctance to test drugs during pregnancy due to regulatory restrictions and litigation risk and the cost of reproductive toxicology studies; a lack of functioning regulatory and pharmacovigilance systems that can help gather data on the use of a drug in pregnancy following its approval; the small market size for conditions affecting pregnant women; the nature of the traditional pharmaceutical business model, which prioritises the pursuit of blockbuster drugs; and gaps in regulatory systems allowing for the wide off-label use of drugs in pregnancy (ibid). The market failure in relation to maternal health has contributed to a lack of drugs being specifically developed for obstetric conditions.

Scope for capacity building

Products developed by pharmaceutical companies must be available, affordable and accessible to women worldwide, especially if they offer superior health outcomes. Beyond developing and adapting the products, pharmaceutical companies can contribute in several other areas. Capacity building is particularly important in low-resource countries where small, low-cost interventions can have a significant impact on care and health outcomes. The best interventions to prevent maternal deaths are: access to a skilled birth attendant, access to emergency obstetrical care in case of complications, and a functional referral system that guarantees emergency care if necessary (IWHP, 2009). To help build local capabilities, companies can, for example, invest in healthcare delivery systems and infrastructure; invest in enabling environments, such as the training of health workers to deliver products; and support community health education. Mobile health applications, eLearning modules and online platforms can increase access to quality education, training and experience sharing. Increasing the skills of healthcare workers can have a significant impact on maternal and child mortality.

Consideration of affordability

Regarding affordability, price is not commonly the most important access barrier to commodities for maternal and reproductive health. For example, a lack of access to maternal health and family planning products can be caused by weak local delivery markets, which can, in turn, be the result of many factors: including a lack of awareness and demand from the provider and patient; breakdowns in the local supply chain and distribution system; or limited local production due to small market sizes and limited profits (UN, 2012). Nevertheless, pharmaceutical companies have a responsibility to ensure their products are equitably priced. The pricing of contraceptive implants has been identified as a key priority area by the UN Commission of Life-Saving Commodities for Women and Children (UN, 2012: 11). Its report also emphasizes the importance of market-shaping activities for lowering prices, such as, for example the efforts of the Clinton Health Access Initiative (CHAI) that have resulted in reduced prices for contraceptives.

Methods and approach

This paper focuses on two main areas of activity where pharmaceutical companies can have an impact on maternal and reproductive health: through their R&D efforts; and through partnerships that aim to improve the availability, affordability and accessibility of relevant products and maternal care. It asks (1) whether and how pharmaceutical companies have committed to achieving the goals set out in the *UN's Global strategy for Women's and Children's Health* in support of MDG 5; and (2) whether and how pharmaceutical companies are operationalizing these commitments or taking other action to achieve MDG 5.

The analyses presented in this research paper are based on data submitted by pharmaceutical companies for the 2014 Access to Medicine Index, supplemented by additional desk research. The Access to Medicine Index independently measures and ranks 20 of the world's largest research-based pharmaceutical companies^{III} on their efforts to improve access to medicine in developing countries. The 20 companies ranked in the 2014 Access to Medicine Index collectively account for more than 50% of the global pharmaceutical market. This paper analyses all company initiatives, pipeline and on-market products and other efforts to improve maternal health that fall within the pre-defined analysis scopes of the 2014 Index, with a limited number of exceptions set out below (Access to Medicine Foundation, 2013; Access to Medicine Foundation, 2014).

The 2014 Index covers the most prevalent maternal health conditions: including abortion, maternal sepsis, maternal haemorrhage, obstructed labour and hypertensive disorders of pregnancy. Contraceptives methods are also included.^{IV} Although not included in the disease scope of the 2014 Index, initiatives targeting obstetric fistula were also included in this analysis, due to the condition's direct link to obstructed labour. On-market products only qualify for analysis if they are currently marketed globally.

Products and initiatives related to the prevention of mother-to-child transmission were excluded from this analysis, even though it is widely recognized that anti-retroviral therapy (ART) can significantly improve health outcomes for both mothers and children. Most maternal deaths among women with HIV/AIDS are due to non-obstetric causes and there is no consensus on the impact of ART on causes, rates and distribution of maternal morbidity and mortality in low and middle-income countries (Lathrop, Jamieson and Danel, 2014).

Findings: How do pharmaceutical companies contribute to achieving MDG 5?

This section focuses on how the 20 pharmaceutical companies in the 2014 Access to Medicine Index address MDG 5 and how they operationalise their commitments to advance the *UN's Global Strategy for Women's and Children's Health* in the area of maternal health and family planning:

- **Company commitments:** eight companies commit to advancing the UN's Global Strategy for Women's and Children's Health; seven of these companies have made commitments that specifically relate to maternal and/or reproductive health.
- **On-market products:** overview of on-market products for maternal health conditions and contraceptive methods
- **Company initiatives:** how do company initiatives target maternal and reproductive health?

Company commitments: 8 companies commit to advancing the UN's Global Strategy for Women's and Children's Health

Eight of the companies included within the scope of the 2014 Access to Medicine Index have made separate commitments to advance the UN's *Global Strategy for Women's and Children's Health* by implementing activities that help to reduce maternal, new-born and child mortality. Seven of these companies have made commitments that specifically relate to maternal and/or reproductive health. An overview of the companies with commitments to maternal health as published by Every Woman, Every Child can be found in Table 4.

Table 4: Commitments relating to maternal health under to the UN's Global Strategy for Women's and Children's Health, via Every Woman Every Child

Company	Commitment
GSK	<ul style="list-style-type: none"> GSK commits to help save the lives of one million children through its partnership with Save the Children. One focus area of the commitment is to deliver medicines and vaccines, especially to pregnant women and new-borns. In 2014 GSK committed to joining an international group of public and private organizations to accelerate the development of an innovative heat-stable and low-cost inhaled form of oxytocin to manage post-partum haemorrhage in resource-poor settings. The company also trains frontline community workers with 20 percent of the profits generated in specific countries.
Johnson & Johnson	<ul style="list-style-type: none"> Johnson & Johnson has made five-year, USD 200 million commitment in response to the United Nations' Global Strategy for Women's and Children's Health. The commitment seeks to increase the life expectancy and quality-of-life and, by the year 2015, it aims to reach at least 120 million women and children per year in 50 countries through the partnership.
Merck & Co.	<ul style="list-style-type: none"> Merck & Co. has committed to implementing Merck for Mothers, a 10-year, USD 500 million initiative to reduce maternal mortality.
Novartis	<ul style="list-style-type: none"> The Novartis Foundation for Sustainable Development has committed to achieving the MDGs through a variety of healthcare programs as well as through efforts to bring different stakeholders together to build effective health partnerships. It developed a training tool for Integrated Management of Pregnancy and Childbirth in collaboration with the WHO and the Swiss Tropical and Public Health Institute (IMPACTt).
Novo Nordisk	<ul style="list-style-type: none"> Novo Nordisk commits to Every Women Every child and other initiatives to advance the prevention of non-communicable diseases (including diabetes) with a focus on improving maternal, new-born and child health. In 2014 it updated its commitment to include a USD 400,000 project that focuses on gestational diabetes mellitus in India.
Pfizer	<ul style="list-style-type: none"> Pfizer commits to advance new-born and maternal health through research, development, and production of science- and biomedical-based innovations, and through partnerships aimed at helping build the capacity needed to facilitate access to care for mothers and new-borns.
Sanofi	<ul style="list-style-type: none"> The Sanofi Espoir Foundation has renewed its commitment to fighting against maternal and neonatal mortality. The Foundation supports new programs to provide midwives with better training, education and working environments. It will also promote worldwide sharing of experiences and ideas through the platform 'Connecting Midwives' which was developed with the International Confederation of Midwives.

Summarised from: UN, 2015b.

On-market products: overview of on-market products for maternal health conditions and contraceptive methods

The 20 companies included in the 2014 Access to Medicine Index collectively have 700 on-market products that fit the criteria of analysis for the Index (i.e., they target diseases within scope of the Index). Only 37 of these (5.3%) address maternal and reproductive health conditions, including 11 antibiotics that are used to treat maternal sepsis, among other conditions (Table 5). This small number can be partially explained by the small market size and fact that there are many generic pharmaceuticals on the market for maternal health conditions. Novartis' portfolio addresses the most maternal health conditions in scope. Roche is the only company that has diagnostics and platform technologies for maternal sepsis and pre-eclampsia on the market. Pfizer has four medicines to treat maternal sepsis and Merck & Co. has two.

Of the 37 products that address maternal health conditions, the 2014 Access to Medicine Index identified 18 relevant on-market contraceptive methods, from four companies: Johnson & Johnson has six contraceptives on the market, both Merck & Co. and Bayer have five and Pfizer has two. This comparably high proportion (49%) can be explained by the large number of women with unmet contraceptive needs and the active promotion of contraceptive use and initiatives by governments and NGOs. The combination of these two factors creates an attractive market for pharmaceutical companies.

Table 5: On-market products included in the 2014 Access to Medicine Index that address maternal and reproductive health^{IV}

Company	Total number of unique products	Products indicated for maternal health conditions ^V				Reproductive health
		Maternal sepsis	Post-partum hemorrhage	Obstructed labour	Hypertensive disorders of pregnancy	Contraceptive methods
Bayer	5					5
Johnson & Johnson	6					6
Merck & Co.	7	2				5
Novartis	8	5	3	3	1	
Pfizer	6	4				2
Roche	5	4			2	
Total	37	15	3	3	3	18

Source: Access to Medicine Index 2014

Company initiatives: 10 companies are implementing initiatives to improve maternal and reproductive health

10 of the 20 companies included in the 2014 Access to Medicine Index are implementing initiatives that aim to improve maternal health and access to family planning products. They are implementing 28 initiatives in total (see Table 6):

- 21 focus on improving maternal health.
- 2 focus on the treatment of obstetric fistula.
- 5 focus on improving access to family planning products.

The companies active here include all seven companies that make a corresponding commitment to EWEC.

Table 6: Overview of companies with on-market products and/or initiatives for maternal and reproductive health.

	Maternal Health					Family Planning	Women's Health	NCDs
	General maternal health	Maternal sepsis	Maternal haemorrhage	Obstructed labour	Hypertensive disorders of pregnancy	Contra-ceptives	Fistula*	Diabetes*
Astellas	■						■	
Bayer						■ ■		
Daiichi Sankyo	■							
GSK	■		■					
Johnson & Johnson	■					■	■	
Merck & Co.	■	■ ■	■			■ ■		
Novartis	■	■	■	■	■			
Novo Nordisk								■
Pfizer	■	■				■ ■		
Roche		■			■			
Sanofi	■							

* There are no pharmaceutical products available for fistula. This analysis does not include products for the treatment of diabetes.

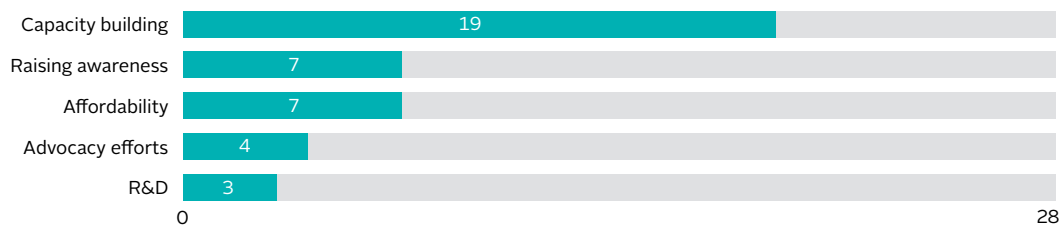
- The company has/ supports initiatives for this condition
- The company has products to treat this condition

The companies with initiatives in the area of family planning are Merck & Co., Pfizer and Bayer. With its Changing Diabetes in Pregnancy program, Novo Nordisk is the only company that addresses a non-communicable disease.

How do company initiatives target maternal and reproductive health?

The 28 initiatives target maternal and reproductive health through one or more of a range of mechanisms. There are three R&D initiatives; seven that include specific references to affordability; 19 that include elements of capacity building; four that include advocacy efforts and seven that focus on raising awareness of maternal health conditions and family planning. Most initiatives (75%) are supported by long-term commitments (>2 years) to improve maternal health. Almost 40% of the initiatives (10 out of 28 initiatives) are aligned with companies' core business activities, making them more likely to be sustainable in the long-term. 15 initiatives are either new or have added new elements to existing programs in recent years. All 28 initiatives involve some sort of partnership with international organisations (e.g., the UN, WHO, USAID), local and/or international NGOs (e.g., Save the Children, AMREF), governments, private sector partners, foundations, universities and/or non-profit organisations (e.g., PATH).

Figure 2: Distribution of the mechanisms used by the 28 initiatives that target maternal and reproductive health.



Few R&D initiatives, mainly targeting post-partum haemorrhage

Three companies are engaged in R&D activities that address maternal and reproductive health: GSK, Merck & Co., and Novartis. All three companies are actively addressing post-partum haemorrhage.

GSK

In 2013, GSK established an R&D unit dedicated to maternal and neonatal health with a remit to develop new medicines for complications arising from pregnancy and childbirth. The Maternal and Neonatal Health Unit has committed to developing, registering and marketing two improved formulations of essential medicines on the WHO Priority Life-Saving Medicines for Women and Children List (2012). One of these is relevant to this study: the company is part of an international group of public and private organisations collaborating to accelerate the development of an innovative heat-stable and low-cost inhaled form of oxytocin to manage post-partum haemorrhage in resource-poor settings. It is being developed and tested for compatibility in GSK's low-cost inhaler platforms. Formulated as a dry powder, inhaled oxytocin eliminates the need for refrigerated storage conditions, is easier to administer by health workers, birth attendants and mothers themselves. This has the potential to support women in low-resource settings who give birth outside of medical facilities.

Merck & Co.

The Merck for Mothers program is engaged in several R&D activities and partnerships that focus on the needs of poor patients in developing countries. In April 2014, Merck & Co. announced that it is collaborating with the WHO and Ferring Pharmaceuticals to advance a new, proprietary formulation of carbetocin, used to prevent post-partum haemorrhage in women after childbirth. It is designed to be stable at room temperature, even in hot and tropical climates, unlike oxytocin, the standard medicine for this condition and which requires a cold chain. If the results of the study are positive, the organisations will work together to make the medicine available in developing countries with a high burden of maternal mortality at an affordable and sustainable public-sector price (Merck & Co., 2014). The company's R&D efforts in the area of family planning also include a temperature-stable contraceptive ring, as well as a longer-acting contraceptive ring, an HIV-preventative ring and a medicated intra-uterine system.

Merck & Co. is the only company that has contraceptive methods in its R&D pipeline: a heat-stable contraceptive ring and an intra-uterine system, which are both being adapted to meet needs in developing countries. For example, the contraceptive rings currently available require supply chains with extensive control measures to prevent the release of hormones and reduction in efficacy during shipment; heat-stable contraceptive rings could be used in remote, tropical and hot regions without cold chains.

Novartis

Novartis is also involved in the development of an inhaled formulation of oxytocin which can overcome barriers associated with injection and a cold chain. Novartis has the most products in its R&D pipeline that address maternal health conditions: a streptococcus B preventative vaccine^{VI} addressing maternal sepsis; relaxin for hypertensive disorders of pregnancy; and an inhaled formulation of oxytocin to treat post-partum haemorrhage.^{VII} A vaccine for streptococcus B is of higher need than methods and tools for screening and testing, as the necessary lab facilities may not be available in resource-limited settings. An inhaled formulation of oxytocin could overcome barriers associated with the current mode of delivery: injection.

25% of initiatives include action on pricing

Seven initiatives from five companies include specific references to affordability of care and/or the pricing of relevant products. Most of this activity can be observed in the area of contraceptives. Bayer, Merck & Co. and Pfizer reduce the prices of select contraceptive methods for public-sector partners in certain countries:

Bayer

Jadelle® Access Program and Contraceptive Security Initiative

One of Bayer's key focus areas is reproductive health and the company has committed to giving women in developing countries the chance of self-determined family planning using hormonal contraceptives. Since January 2013, under the Jadelle® Access Program, acting in partnership with The Clinton Health Access Initiative (CHAI), Bayer has reduced the price for its long-acting (for up to 5 years) reversible contraceptive implant Jadelle® (levonorgestrel) by more than 50%, from US\$18 to US\$8.50 per implant. As part of the initiative, the Bill & Melinda Gates Foundation has provided a market guarantee, assuring funding for at least 27 million implants for women in developing countries over the next six years.

The company is also working with USAID to achieve affordable access to its oral contraceptive Microgynon Fe® (ethinylestradiol/levonorgestrel/ferrous fumarate) in 11 countries in sub-Saharan Africa. Bayer has agreed a price point with USAID that is above the social marketing and public sector level and below commercial prices, which will help to ensure the sustainability of this market approach beyond USAID funding. Bayer has committed to maintaining this price point over time and to continuing to offer the product beyond the formal end of the projects' contract period. The initiative has been launched in Ethiopia, Uganda, Tanzania, Rwanda, Ghana, Kenya and Malawi.

Merck & Co.:

Implanon® Access Initiative

In May 2013, Merck & Co. and its public-sector partners expanded the Implanon® Access Initiative. Under this agreement, the company is reducing the price of the implant and its next generation (Implanon NXT® (etonogestrel)) by approximately 50% for the next six years in the 70 poorest eligible countries.^{VIII} This reduced price will be available to intermediary procurement agencies, country governments or other organisations. It also works with implementing organisations and partners to provide technical support to improve service delivery infrastructure and the training of healthcare workers. Registrations or special waivers are in place for Implanon® (etonogestrel) and Implanon NXT® in about 60% of all eligible FP2020 countries and the company aims to expand this to 75% by end 2014

Pfizer

Sayana® Press^{IX} price reduction

Sayana® Press (medroxyprogesterone acetate) is an injectable contraceptive (effective for at least 13 weeks) packaged in a pre-filled single-use syringe developed by PATH. This allows the injection to be administered by healthcare workers to women in their homes or other convenient settings. It has the potential to expand the availability of injectable contraceptives in remote areas. Pfizer is

a member of a public-private partnership working to introduce Sayana® Press in Senegal, Uganda, Burkina Faso, Niger and Bangladesh (USAID, 2014). The partnership is coordinated by PATH, which also leads implementation on the ground. The other members are: the Bill & Melinda Gates Foundation, the Children's Investment Fund Foundation, DFID, UNFPA and USAID. In November 2014, the partnership announced an agreement that will expand access for women most in need in 69 of the world's poorest countries. Through this collaboration, Sayana® Press will be sold for US\$1 per dose to qualified purchasers who can help enable women in these countries to access the contraceptive at reduced or no cost.

Other initiatives that consider affordability are: Merck & Co.'s efforts to improve the quality, affordability and accessibility of care from private providers (part of Merck for Mothers); Novartis' initiative to support primary healthcare in Mali; and GSK's efforts to develop a heat-stable, low-cost inhaled form of oxytocin.

Majority of initiatives have a strong focus on local capacity building

19 initiatives from nine companies, out of 28 initiatives in total, have a strong focus on local capacity building. Notable examples include:^X

Johnson & Johnson

Focus on obstetric fistula

Johnson & Johnson is working with partners to prevent and treat fistula, aiming to build the capacity of birth attendants to manage emergency obstetric and newborn care through a four-year partnership with the Health 4+ (WHO, UNFPA, UNICEF, UNWomen, World Bank, UNAIDS) in Ethiopia, Tanzania and Zanzibar. The company's partnership is training Integrated Emergency Obstetric Surgeons, nurses and midwives. In addition, it collaborates with FIGO (the International Federation of Gynaecology and Obstetrics), to train fistula surgeons.

GSK

Reinvesting to train front-line health workers

GSK is re-investing 20% of its profits made in Least Developed Countries in the countries themselves. This program focuses on training frontline health workers in order to reduce child and maternal mortality and to address wider health needs. For example, in Bangladesh the company is working to increase the number and capacity of community health workers in the Sunamganj district of North East Bangladesh and in the slums of Dhaka. In Nepal, the company has invested in a program to increase access to maternal healthcare in rural areas by strengthening the capacity of health service providers and health facilities for improved maternal and new-born health facilities in Kailali and Doti districts. It targeted 400 Community Healthcare Workers and 1,750 additional female community volunteers over three years (2010-2013).

Capacity building: three mobile health applications

Three initiatives from two companies focus on improving maternal health through m-Health applications: MAMA from Johnson & Johnson; and two initiatives supported by the Sanofi Espoir Foundation. Over 64 percent of all mobile phone users live in developing countries. This creates the opportunity to leverage m-Health applications for maternal health, in particular in developing countries as it can overcome critical health system constraints. M-Health applications can facilitate emergency medical responses, point-of-care support, health promotion and data collection (Tamrat and Kachnowski, 2012). Evidence indicates that mobile technology is an effective tool that empowers women and healthcare providers (ibid).

Johnson & Johnson

Information sharing for awareness raising

In 2010, Johnson & Johnson set itself the goal of delivering m-Health programs in six countries with high maternal mortality rates and high mobile-phone penetration: Bangladesh, China, India, Mexico, Nigeria and South Africa. Through its Mobile Alliance for Maternal Action (MAMA)^{XI} the company distributes culturally-sensitive health messages at specific milestones during pregnancy and newborn development. It aims to create awareness about disease prevention and when to get health check-ups and care. It provides advice on topics such as good nutrition during pregnancy, how to prepare for childbirth, and recognizing signs of troubles which can lead to difficulties in labour and delivery.

Sanofi

Building networks and enabling monitoring

In Benin, the Sanofi Espoir Foundation is supporting the international relief agency CARE in building a participatory approach for village communities and to connect different actors in the health system using a mobile application for sharing messages about education and prevention. This is intended to enable better monitoring of pregnant women and the roll-out of rapid alerts to health centres in emergencies. It involves 35 villages, potentially benefitting 25,253 women.

Capacity building: six eLearning and online platforms

There are six initiatives, from Sanofi, Novartis and GSK, to develop eLearning programs and online platforms that can be used by midwives for training purposes and to share experiences and insights.

Novartis

E-learning on IMPACtt

Novartis has contributed to the development of an innovative e-learning tool for training in the Integrated Management of Pregnancy and Childbirth (IMPACtt) approach developed by the WHO. The tool aims to improve the effective application of simple, low-cost interventions by healthcare workers and will comprise courses on the topics of antenatal care, child-birth care, newborn care and postnatal care for mother and baby. The first module of IMPACtt, on Essential Newborn Care, has been finalized and tested in Tanzania (2012) and the Philippines (2013). Other modules are under development and the antenatal care module was tested in 2014. The tool is offered for free, and focuses specifically on Tanzania, Mali, Burkina Faso, Cameroon and the Philippines.

Sanofi

Connecting midwives to pool expertise

Through its partnership with the International Confederation of Midwives (ICM), the Sanofi Espoir Foundation is supporting the launch of the “Connecting Midwives” web platform. This platform is intended to provide midwives with an online space to share experiences, and discuss and pool ideas, projects and innovations. In addition, the platform will reward ten field initiatives to improve maternal and neonatal health, as part of the Sanofi Espoir Foundation’s Awards for Midwives. The Sanofi Espoir Foundation has allocated €2.5 million in 2013 to addressing maternal and neonatal mortality, and a total amount of €3.6 million for the period of 2010 to 2015, in support of 13 long-term programs.

10 initiatives aligned with core business activities

Initiatives that go beyond only philanthropy and are linked to companies' core business activities are more likely to be sustainable in the long-term. Out of 28 initiatives, 10 are aligned with companies' core business activities. Notable examples include:^{XII}

Merck & Co.

Integrated approach linking R&D, in-country programs and awareness

In 2011, the company launched its 10-year, US\$500 million Merck for Mothers program as part of its global commitment to reduce maternal mortality. Taking an integrated approach, the initiative includes product innovation, in-country initiatives that tackle specific access barriers, and awareness raising activities. It addresses the two leading causes of maternal mortality: post-partum haemorrhage and pre-eclampsia (hypertensive disorders). It also focuses on family planning. The program is global but has six priority countries: Brazil, India, Senegal, Uganda, the US and Zambia. Merck for Mothers has supported more than 30 maternal health projects in countries around the world. As part of the Merck for Mothers program, it also maintains a philanthropic initiative, Global Giving, to support maternal health initiatives in their regions.

The three pillars of the program are:

1. Product innovation

Merck & Co. is evaluating opportunities to advance the development of innovative technologies and products that have the greatest potential to save women's lives. The company supported an evaluation by PATH of nearly 40 technologies designed to ensure safe pregnancy and childbirth in settings with limited infrastructure. This has resulted in the creation of a novel assessment tool that can help inform decisions about which technologies to invest in to improve maternal health.

2. Access to affordable, quality care

The company supports programs in countries and regions with high rates of maternal mortality to expand access to maternal health solutions and establish models for care that are effective, sustainable and long-lasting. It works closely with country governments.

• India

In India, Merck & Co. is working to improve the quality, affordability and accessibility of care from private providers, recognizing that 80% of the population in India seek care from private providers. The company expects to reach nearly 500,000 women over the next three years in India.

• Uganda and Zambia

In Uganda and Zambia, programs complement the efforts of a public-private partnership to reduce deaths during pregnancy and childbirth, of which Merck & Co. is a founding partner (*Saving Mothers, Giving Life*). In 2013, Merck & Co. launched the Merck for Ugandan Mothers program, a partnership with Population Services International and its local affiliate, the Program for Accessible Health, Communication and Education (PACE), to improve the private delivery of maternal healthcare in up to 30 districts in Uganda. The program is expected

to reach more than 150,000 pregnant women over three years. In its first year, PACE (1) expanded its franchise of private healthcare providers to include nearly 40 new clinics and trained and mentored more than 80 providers in delivering maternal healthcare; (2) trained 129 drug-store owners to provide essential maternal health products, facilitate referrals and promote clean delivery kits; (3) established 26 "mothers clubs" to encourage women to save for childbirth costs; and (4) recruited and trained 121 Mama Ambassadors (community health workers).

The programs demonstrate good results in the first year: 30% reduction in maternal mortality in Uganda target districts and 35% in Zambia target facilities and a significant increase in facility deliveries in target districts (62% in Uganda and 35% in Zambia), fewer stock-outs of essential medicines, improved referral networks, infrastructure upgrades and strengthened quality of care.

- **Senegal**

In Senegal, Merck & Co. participates in a pilot led by IntraHealth and funded by the Bill & Melinda Gates Foundation to improve the availability of contraceptives through the "Informed Push Model". This logistics approach focuses on the last mile of distribution, using teams of trained staff to visit health facilities, review inventory and restock shelves.

- **Brazil**

In Brazil, the company works closely with the government to conduct a survey of health providers and administrators in hospitals to assess the causes of maternal deaths in these settings. Based on the findings, it will develop initiatives to improve quality of care.

3. Awareness and Advocacy

In addition to its R&D efforts and in-country initiatives, the company also aims to raise public awareness of maternal mortality. Its advocacy efforts focus on accelerating progress in finding solutions to the challenges of maternal mortality.

Novo Nordisk

Diabetes in pregnancy

In 2009, Novo Nordisk launched its Changing Diabetes in Pregnancy program in support of MDG 3, MDG 4 and MDG 5. The program focuses on three key elements:

1. Evidence gathering and advocacy: increasing awareness of the links between gestational diabetes and NCDs, maternal and child health and sexual and reproductive health and rights in the international community and internal awareness raising;
2. Efforts to help define standards and guidelines for gestational diabetes management; and
3. Supporting local demonstration projects to promote on-the-ground awareness, screening and capacity building activities focusing on pregnant women in low- and middle-income countries.

Maternal health initiatives concentrated in sub-Saharan Africa

Most initiatives focus on improving maternal and reproductive health in sub-Saharan Africa, with Tanzania receiving the most attention (from 8 initiatives), followed by Ethiopia (from 5 initiatives), then Kenya, Senegal and Uganda (from 4 initiatives each). Countries in South America receive the least attention from pharmaceutical companies with regard to maternal health. Single initiatives were observed in Brazil, Colombia and Nicaragua. In Asia, most activity is observed in Bangladesh and India (from 3 initiatives each).

Initiatives that focused on improving the accessibility and affordability of contraceptive methods have the widest geographical scopes. For example, Merck & Co.'s Implanon® (etonogestrel) initiative offers reduced prices for its contraceptive implant in 70 countries, while Bayer's Jadelle® (levonorgestrel) access program reduces prices in over 50 countries. These priority countries have been set by FP2020.

Majority of initiatives are new or recently expanded

15 initiatives are either new or have added new elements to existing programs since the previous Access to Medicine Index was published in 2012. For example, in May 2014, Astellas announced a US\$2 million donation to the Fistula Foundation to provide treatment to women suffering from obstetric fistula in Kenya. The program aims to deliver surgery to 1,200 women in Kenya over the next three years. The Sanofi Espoir Foundation supports six projects that were launched in the second half of 2013. By 2015, these projects will have trained 4,200 midwives in Ethiopia, Tanzania, Senegal, Côte d'Ivoire, Burma, Cambodia and Mexico. They will also help to strengthen the health policies of these countries. The Sanofi Espoir Foundation will support these programs for an initial three-year phase and aim to increase the number midwives' skills by improving training conditions, working to retain them in their jobs, and assigning them to high-need areas. In 2013, GSK and Save the Children announced a strategic partnership, with signature programs in the Democratic Republic of Congo and Kenya that focus on improving neonatal, maternal and child health.

Discussion

This is the first attempt to document the activities and initiatives that pharmaceutical companies are undertaking to help achieve MDG 5. Pharmaceutical companies have a unique role to play, as they can develop much-needed new and adapted products to meet the specific needs of women living in developing countries. In addition, they can contribute in other areas such as capacity building, infrastructure development and through other (financial) on-the-ground support. Based on this analysis, it can be concluded that 10 large research-based pharmaceutical companies are committed to and actively contribute to achieving MDG 5. Considering the fact that only five of these 10 companies currently have products in the area of maternal health and/or family planning, it shows commitment from the industry.

Despite limited R&D activity, highest R&D needs are being addressed

The latest G-Finder report (Policy Cures, 2015) has identified several reproductive health R&D gaps specific to developing countries, including adapted drugs for post-partum haemorrhage (PPH), a high-priority target, and adapted drugs, devices and combination products for contraception. With regard to R&D for maternal health conditions, limited industry activity can be observed from the 20 companies included in the Index. Only three companies are active here, all focusing on post-partum haemorrhage. Currently, intravenous or intramuscular injection of oxytocin is the accepted gold standard for the prevention and treatment of post-partum haemorrhage and is an essential medicine recommended by the WHO. However, it is not suitable for use in developing countries due to the instability of the formulation at room temperature and due to the fact it has to be administered by a skilled birth attendant (Policy Cures, 2015). Current R&D gaps for post-partum haemorrhage that are specific to developing countries include (ibid):

- Formulations of oxytocin and oxytocin analogues that are heat-stable and do not require intravenous or intramuscular administration.
- Blood-clotting drugs that specifically affect uterine bleeding and that are appropriate for use in developing countries.

Novartis, GSK and Merck & Co. are active in this area: Novartis is developing an inhaled form of oxytocin and GSK is working as part of an international group of public and private organisations to accelerate the development of a heat-stable and low-cost inhaled form of oxytocin. Merck & Co. is collaborating with the WHO and Ferring Pharmaceuticals to advance a new, proprietary formulation of carbetocin, used to prevent post-partum haemorrhage and designed to be stable at room temperature. If these products reach the market, they could have a significant positive impact on lowering maternal mortality rates in developing countries, as the condition is the most significant contributor to maternal mortality and morbidity worldwide and disproportionately affects women in low-resource settings.

A recent report (Policy Cures, 2015) found that the majority of funding in the area of maternal and reproductive health went to developing-world-focused contraceptives, for which the pharmaceutical industry was the largest funder (ibid). Current R&D gaps for contraceptives that meet needs specific to developing countries include:

- Contraceptives that are usable on demand (around time of intercourse, and potentially without a partner's knowledge or cooperation);
- Contraceptives that are safe to use while breast-feeding;
- New, long-acting, reversible contraceptives;
- Non-hormonal contraceptives; and
- Non-surgical permanent contraception.

Merck & Co. is the only company actively developing adaptive contraceptive methods that are suitable for use in developing countries: a heat-stable contraceptive ring and an intra-uterine system. However, other companies are already addressing current contraceptive R&D needs through their existing products. For example, Bayer and Merck & Co. aim to ensure wide availability and affordability of their long-acting, reversible contraceptives Jadelle[®] (levonorgestrel, Bayer) and Implanon[®] (NXT) (etonogestrel, Merck & Co.) through cooperation with international organisations and procurers. Pfizer's Sayana[®] Press (medroxyprogesterone acetate) injectable contraceptive allows healthcare workers to deliver injections to women at home or in other convenient settings, which has the potential to expand availability of injectable contraceptives in remote areas. The most commercially viable initiatives appear to be in the area of contraceptives due to donor funding and significant unmet needs in developing countries for contraceptives, creating attractive markets.

Although the percentage of the total R&D pipeline devoted to the development of products addressing maternal health conditions and contraceptives remains relatively low, some companies are addressing the highest-need reproductive health R&D gaps (Merck & Co., GSK and Novartis). For many other maternal health conditions, however, there is less need for specific R&D, and other interventions, such as training midwives, increasing facility deliveries and/or increasing the availability of existing medicines at health facilities, can be more effective solutions.

Pharmaceutical companies partner to improve maternal health and access to family planning

The UN's *Global Strategy for Women's and Children's Health* calls upon the global community to work together to enhance financing, strengthen policy and improve services on the ground for the most vulnerable women and children. Based on our analysis it can be concluded that all relevant 28 initiatives involve some sort of partnership with international organisations (e.g., the UN, WHO, USAID), local and/or international NGOs (e.g., Save the Children, AMREF), governments, private sector partners, foundations, universities and/or non-profit organisations (e.g., PATH). This suggests that addressing maternal health and family planning is best done in collaboration, in order to share incentives, reduce risk and to make sure activities are aligned with local needs.

Based on the analysis, it can be observed that partnerships can serve different purposes. For example, we observe several PDPs (product development partnerships) wherein both the knowledge and strengths of the private and public sectors are exploited to find the most efficient and effective solutions (e.g., Merck & Co. and PATH; GSK and Monash University, McCall MacBain Foundation, Grand Challenges Canada and Planet Wheeler Foundation), as well as on-the-ground partnerships to improve local capacities (e.g. Sanofi and AMREF in Senegal and Côte d'Ivoire).

In addition, we find that partnerships can be important tools for shaping global markets by securing demand, supply and prices. The UN Commission on Life-Saving Commodities for Women and Children (2012) formulated the negotiation of multi-year volume guarantees of contraceptive implants with appropriate pricing on behalf of donors with one or more manufacturers as one of the key priority activities. We find that companies with contraceptive methods in their product portfolios (Bayer, Merck & Co. and Pfizer) are actively involved in these kinds of partnerships.

Geographic scope of activities

Pharmaceutical companies focus their activities on 35 countries. Half of the 40 countries with the highest mortality ratios (WHO, 2014d) are addressed by pharmaceutical companies' efforts to improve maternal health and access to family planning products. Companies can do more to improve maternal health in countries with the highest need such as Sierra Leone, Chad, the Central African Republic, Somalia, the Democratic Republic of Congo and Burundi, where maternal mortality ratios are highest. Limited company activity in these areas can partly be explained by the fact that these markets are less attractive for pharmaceutical companies and therefore activities would mainly be philanthropic in nature.

Company commitments to Every Women Every Child

All seven companies that publically commit to advancing the UN's *Global Strategy for Women's and Children's Health* are actively contributing to improving maternal health and access to family planning products. The scale and scope of their activities is, in general, broader than for companies that have not made public commitments. Typically, companies active here are also those with the most relevant on-market and pipeline products. Roche is the only company with relevant products (diagnostics for maternal sepsis) that has not made a commitment or set up any initiative for improving maternal health. There are companies active in this area that do not have relevant products: Astellas, Daiichi Sankyo, Novo Nordisk and Sanofi. For example, although Sanofi has no relevant products in this area, it is actively supporting midwives to reduce maternal health and neonatal deaths in developing countries. Although Bayer has not made a public commitment to the *Global Strategy* it is actively working to increase access to its contraceptive products in developing countries together with its partners.

Conclusion: action follows commitment

This report compares pharmaceutical companies' commitments to achieving MDG 5 with their efforts to operationalise these commitments. Within the scopes of the 2014 Access to Medicine Index, it maps pharmaceutical companies' commitments to advancing the UN's Global Strategy for Women's and Children's Health to improve access to maternal and reproductive health against their on-market and pipeline products and their access initiatives relevant to this focus area.

Based on this analysis, there is a correlation between the companies that commit publically to improving access to maternal and reproductive health and those that also take action. It is particularly encouraging to see that companies without relevant products also support and implement initiatives aligned with the targets set in MDG 5. This supports the view that research-based pharmaceutical companies can contribute in the area of health systems strengthening.

- 1 Companies active here are also those with the relevant on-market and pipeline products. However, there are also companies active in this area that do not have relevant products.
- 2 Companies actively partner with public sector and other partners to improve service delivery and infrastructure. All relevant initiatives involve some sort of partnership with international organisations, local and/or international NGOs, governments, private sector partners, foundations, universities and/or non-profit organisations.
- 3 Companies are actively investing in projects aimed at improving maternal health and access to family planning (including philanthropy) and are addressing the affordability of contraceptive methods with public partners in order to increase accessibility.
- 4 Companies are ensuring community outreach and awareness raising and are actively investing in building local capabilities.
- 5 The level of R&D activity is limited, yet the highest-need R&D gaps are being addressed.

Together with experienced and independent partners, pharmaceutical companies are encouraged to: 1) leverage relevant R&D expertise and know-how; 2) evaluate the impact of existing initiatives and their long-term sustainability; 3) expand existing commitments and activities in this area where deemed appropriate and effective; and 4) actively evaluate new methods for addressing the specific challenges set out in the forthcoming SDGs.

Action to improve maternal and reproductive health clearly starts with an international will to act from multiple parties, underpinned by a high degree of clarity regarding the appropriate role for each stakeholder, including pharmaceutical companies. The MDGs will conclude this year and be replaced by the SDGs. As stakeholders work toward achieving these new goals, rigorous monitoring and benchmarking will continue to be crucial for identifying what works in the long-term and what needs to be adapted. This report can be used as a baseline for monitoring whether and how individual research-based pharmaceutical companies are working to improve access to maternal and reproductive health.

Appendix About the Access to Medicine Index

This findings in this report are based on the analysis of data submitted by pharmaceutical companies to the 2014 Access to Medicine Index. The Access to Medicine Index independently ranks 20 of the world's largest pharmaceutical companies by revenue on their efforts to improve access to medicine for people living in developing countries. Funded by the Bill & Melinda Gates Foundation and the UK and Dutch governments, the Index has been published every two years since 2008.

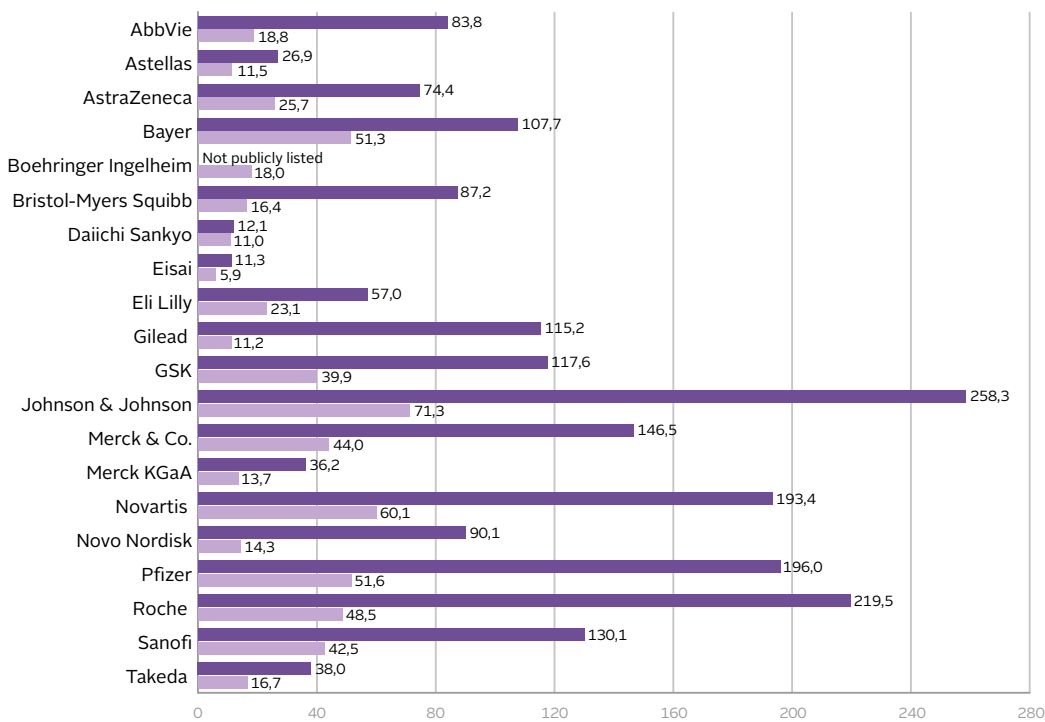
By publicly recognising companies' access-related policies and practices, the Index raises awareness of relevant issues within pharmaceutical companies and provides them with a transparent means of assessing, monitoring and improving their own performances as well as their public and investment profiles. Consistent iterations of the Index highlight industry trends and provide a basis for multi-stakeholder dialogue and solution building.

The Access to Medicine Index uses a weighted analytical framework to consistently capture and compare data from the top 20 research-based pharmaceutical companies across a set of countries, diseases and product types. For each successive Index, the Index research team works with independent representatives of relevant stakeholder groups to refine this framework, to confirm the robustness and usefulness of our analysis, and align it with developments in the access-to-medicine landscape and pharmaceutical industry. The framework is constructed along seven areas of focus, which cover the range of company business activities that experts consider most relevant to access to medicine. Within each area, the Index assesses four aspects of company action: commitment, transparency, performance and innovation.

Analysis scopes for the 2014 Access to Medicine Index

Company scope

Figure 3: 2014 Index company scope

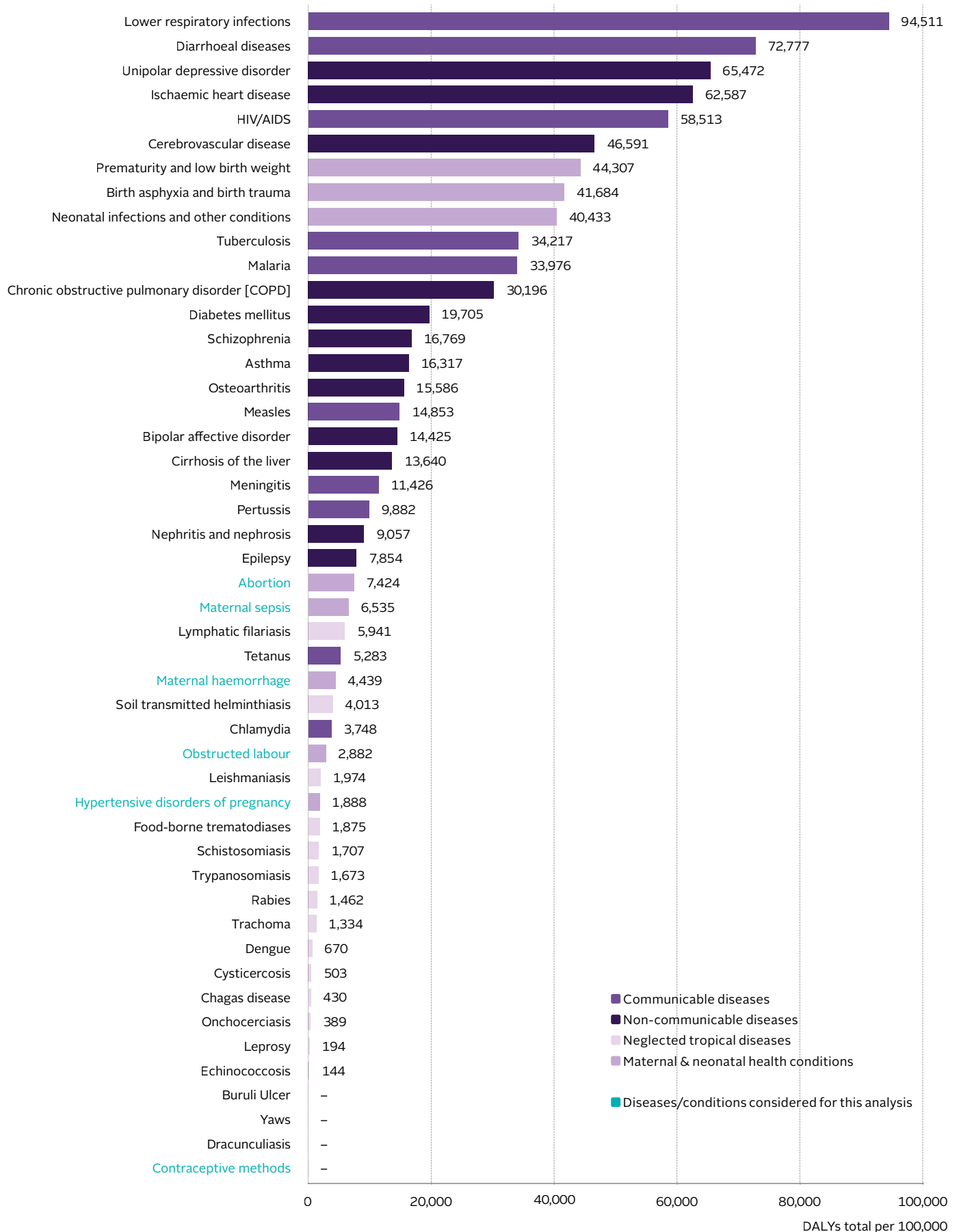


The companies covered by the Index account for more than 50% of the global pharmaceutical market.

■ Market cap as at 31 Dec 2013, Japanese companies as at 31 Mar 2014 (From Thomson Reuters 2014).
 ■ Total 2013 revenue

Disease scope

Figure 4: DALYs of diseases in the 2014 Access to Medicine Index



Country scope

Table 7: List of countries included in the 2014 Access to Medicine Index – 106 countries

Country	Classification	Country	Classification	Country	Classification	Country	Classification
East Asia & Pacific		Suriname	MHDC	Liberia	LIC	Countries removed since	
Cambodia	LIC*	Venezuela, RB	HiHDI	Madagascar	LIC*	2012 Index	
China	MHDC	Middle East & North Africa		Malawi	LIC*	Algeria	HHDC
Fiji	MHDC	Djibouti	LMIC*	Mali	LIC*	Marshall Islands	UMIC
Indonesia	LMIC	Egypt, Arab Rep.	LMIC	Mauritania	LMIC*		
Kiribati	LMIC	Iraq	MHDC	Mozambique	LIC*		
Korea, Dem. Rep.	LIC	Jordan	MHDC	Namibia	MHDC		
Lao PDR	LMIC*	Morocco	LMIC	Niger	LIC*		
Micronesia, Fed. Sts.	LMIC	Syrian Arab Rep.	LMIC	Nigeria	LMIC		
Mongolia	LMIC	West Bank and Gaza	LMIC	Rwanda	LIC*		
Myanmar	LIC*	Yemen, Rep.	LMIC	São Tomé and Príncipe	LMIC		
Papua New Guinea	LMIC	South Asia		Senegal	LMIC*		
Philippines	LMIC	Afghanistan	LIC	Sierra Leone	LIC*		
Samoa	LMIC*	Bangladesh	LIC*	Somalia	LIC		
Solomon Islands	LMIC*	Bhutan	LMIC	South Africa	MHDC		
Thailand	MHDC	India	LMIC	South Sudan	LIC		
Timor-Leste	LMIC	Maldives	MHDC	Sudan	LMIC		
Tonga	MHDC	Nepal	LIC*	Swaziland	LMIC		
Tuvalu	LDC	Pakistan	LMIC	Tanzania	LIC*		
Vanuatu	LMIC*	Sri Lanka	LMIC	Togo	LIC*		
Vietnam	LMIC	Sub-Saharan Africa		Uganda	LIC*		
Europe & Central Asia		Angola	LHDC*	Zambia	LMIC*		
Armenia	LMIC	Benin	LIC*	Zimbabwe	LIC		
Georgia	LMIC	Botswana	MHDC				
Kosovo	LMIC	Burkina Faso	LIC*				
Kyrgyz Rep.	LIC	Burundi	LIC*				
Moldova	LMIC	Cameroon	LMIC				
Tajikistan	LIC	Cape Verde	LMIC				
Turkmenistan	MHDC	Central African Rep.	LIC*				
Ukraine	LMIC	Chad	LIC*				
Uzbekistan	LMIC	Comoros	LIC				
Latin America & Caribbean		Congo, Dem. Rep.	LIC*				
Belize	MHDC	Congo, Rep.	LMIC				
Bolivia	LMIC	Côte d'Ivoire	LMIC				
Brazil	HiHDI	Equatorial Guinea	MHDC				
Colombia	HiHDI	Eritrea	LIC				
Dominican Rep.	MHDC	Ethiopia	LIC				
Ecuador	HiHDI	Gabon	MHDC				
El Salvador	LMIC	Gambia, The	LIC*				
Guatemala	LMIC	Ghana	LMIC				
Guyana	LMIC	Guinea	LIC*				
Haiti	LIC*	Guinea-Bissau	LIC*				
Honduras	LMIC	Kenya	LIC				
Nicaragua	LMIC	Lesotho	LMIC*				
Paraguay	LMIC						

LIC: Low-income Country
World Bank income classification

LMIC: Lower-middle-income Country
World Bank income classification

LDC: Least Developed Country
UN Human Development Index

LHDC: Low Human Development Country
UN Human Development Index

MHDC: Medium Human Development Country
UN Human Development Index

HiHDI: High Human Development Country with high inequality
UN Inequality-Adjusted Human Development Index

* LDC with WTO membership

■ 5 Countries newly included countries in the 2014 Index scope

■ 2 Countries removed from the Index scope

Product scope

The product type scope for Index 2014 remains necessarily broad to capture the wide-ranging product types available to support prevention, diagnosis and treatment of Index Diseases in the Index countries.

It draws closely from the definitions provided by the G-Finder 2012 Neglected Disease Research and Development: A Five Year Review,⁵ and remains unchanged from the 2012 and 2010 Indices.

Medicines

All innovative and adaptive medicines, branded generics and generic medicines used to directly treat the target pathogen or disease process, regardless of formulation, are included. Medicines used only for symptomatic relief are not included.

Microbicides

These include topical microbicides intended to prevent HIV.

Therapeutic vaccines

This covers vaccines intended to treat infection.

Preventive vaccines

This covers vaccines intended to prevent infection.

Diagnostics

Diagnostic tests designed for use in resource-limited settings (cheaper, faster, more reliable, greater ease of use in the field) are included.

Vector control products

These include pesticides, biological control compounds and vaccines targeting animal reservoirs. Only chemical pesticides intended for

global public health use and which specifically aim to inhibit and kill vectors that transmit diseases relevant to the Index are included. Likewise, only biological control interventions that specifically aim to kill or control vectors that transmit Index-relevant diseases are included. Only veterinary vaccines specifically designed to prevent animal-to-human transmission of diseases covered by the Index are included.

Platform technologies

Only those products directed specifically at meeting the needs of countries covered by the Index are included. These comprise general diagnostic platforms, adjuvants and immunomodulators, and delivery technologies and devices.

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Endnotes

- I *Every Women Every Child* is a global movement that mobilises and intensifies international and national action by governments, multilaterals, the private sector and civil society to address the major health challenges facing women and children (UN, 2015a). It focuses on the poorest countries of the world: Afghanistan, Bangladesh, Benin, Burkina Faso, Burundi, Cambodia, Central African Republic, Chad, Comoros, Democratic Republic of the Congo, Côte d'Ivoire, Eritrea, Ethiopia, The Gambia, Ghana, Guinea, Guinea-Bissau, Haiti, Kenya, Democratic Republic of Korea, Kyrgyz Republic, Lao People's Democratic Republic, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Nigeria, Pakistan, Papua New Guinea, Rwanda, Sao Tome and Principe, Senegal, Sierra Leone, Solomon Islands, Somalia, Tajikistan, Togo, Uganda, United Republic of Tanzania, Uzbekistan, Viet Nam, Yemen, Zambia and Zimbabwe. The Commission included a 50th: India.
- II MDG 8E: In cooperation with pharmaceutical companies, provide access to affordable essential medicines in developing countries.
- III Companies included in the Index are: AbbVie, AstraZeneca, Astellas, Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Daiichi Sankyo, Eisai, Eli Lilly, Gilead, GlaxoSmithKline, Johnson & Johnson, Merck & Co., Merck KGaA, Novartis, Novo Nordisk, Pfizer, Roche, Sanofi, Takeda.
- IV For R&D products, the Index applies inclusion criteria based upon the disease classes the product targets. All products were included for adaptive R&D for all four disease classes. For innovative R&D products that target maternal and neonatal health conditions, stricter criteria are applied for inclusion. Supporting evidence to indicate how the product would be made accessible to people living in countries within scope was required. All R&D had to be ongoing during a part or the entire period of analysis. On-market products, submitted by the companies for the 2014 Index, were assessed for their suitability for use under the disease indication(s) as described by the company, and as covered by the ICD10 codes. Product indications were verified using information from regulatory authorities (such as the FDA and EMA), WHO treatment guidelines, company websites and scientific publications.
- V Please note that these products may have multiple indications and can thus be counted multiple times.
- VI In April 2014 it was announced that Novartis would sell its global vaccine business (excluding influenza vaccines) to GSK.
- VII Additional R&D projects were identified after the period of analysis. These initiatives are listed below.
- VIII The countries included under the arrangement are those identified by the external reproductive health community during the July 2012 London Family Planning Summit. This includes the 69 poorest countries, plus India.
- IX This program was launched after the period of analysis for the Access to Medicine Index.
- X Examples were selected based on several criteria, including data free of Non-Disclosure Agreements, where data was detailed or available in the public domain, and the example was not previously mentioned in this paper.
- XI MAMA is founded by Johnson & Johnson with USAID, United Nations Foundation, BabyCenter, and mHealth Alliance.
- XII Examples were selected based on several criteria, including data free of Non-Disclosure Agreements, where data was detailed or available in the public domain, and the example was not previously mentioned in this paper.



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