

## Working Together for the Health of Mothers and Children

### The Issue

Each year 275,000 women die in pregnancy or childbirth. About 6.2 million children die from preventable causes before their fifth birthday, 40% of whom are newborns. The vast majority of these deaths occur in low and middle income countries.

Thanks in part to the focus created by the Millennium Development Goals (MDGs), some progress is being made. Nearly 41% fewer children died before their fifth birthday in 2011 compared to 1990, and the World Health Organization (WHO) has recently reported that maternal mortality has dropped by 45% since 1990.

Despite this progress, much more still needs to be done on both fronts. The lack of progress stems from a broad failure by policy-makers and other stakeholders to prioritise women and children's health and to recognise that they disproportionately suffer from multiple dimensions of poverty. Progress is also limited due to a lack of implementation of specific interventions, proven to significantly increase their chances of survival. Such interventions include robust health systems which incorporate basic vaccination for children and the presence of a skilled healthcare practitioner for all women during delivery.

Although countries have made substantial progress in strengthening many aspects of health systems, there still remain significant inequalities in access to maternal and child healthcare. Progress toward achieving universal health coverage in the new post 2015 agenda is tied to reforming how health systems are financed, improving governance structures, strengthening health infrastructure and delivery, utilising health information technology, ensuring access to innovative and essential medicines, improving health literacy and reshaping the health workforce. Within this framework, the global community must maintain and increase momentum to improve the health of mothers and children.

For decades, GSK has produced safe and effective products to help reduce the burden of disease and improve the lives of mothers and children. With our partners, we are constantly challenging our business model to find new ways of researching and delivering our products in order to provide sustainable solutions that reduce mortality in mothers and children and break the cycle of decline from illness. Better health leads to better economic development. If we keep mothers and their families well now, we can improve the health and economy of future generations. With mortality rates falling rapidly but fertility rates declining at a lower rate, developing countries will experience an increase in the size of their working-age population in the next few decades. This presents them with a critical window of opportunity to boost economic development, known as the 'demographic dividend' as discussed in Save the Children's Food for Thought report<sup>1</sup>. To capitalise on this, developing countries must be encouraged to invest in the health and skills of their future workforce.

GSK is committed to playing our part in the global effort to reach MDGs 4 and 5. However, companies like GSK cannot tackle this challenge alone. No single organisation can make a meaningful difference to the health of mothers and children in isolation, especially in the developing world. Responsibilities need to be shared across governments, multilateral organisations, civil society and the private sector, including the pharmaceutical industry.

This paper identifies key areas for action - with a particular focus on developing countries – for all stakeholders, including GSK.

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<sup>1</sup> [http://www.savethechildren.org.uk/sites/default/files/docs/Food\\_for\\_Thought\\_UK.pdf](http://www.savethechildren.org.uk/sites/default/files/docs/Food_for_Thought_UK.pdf)

### GSK's Position

- **Concerted action is required to support the development of paediatric medicines.** The market for paediatric medicines is inevitably more limited than the adult market. As a result, there are far fewer paediatric indications than adult indications for medicines. A number of steps have been taken to address this, including the introduction of incentives for new research. These need to be expanded and built upon.
- **There needs to be a greater focus on the development of products to treat diseases affecting women.** GSK has pledged to address diseases affecting women. We are developing a novel treatment (*Retosiban*) to halt pre-term labour and delay delivery in women with uncomplicated pre-term labour. In 2013, we announced a new commitment to the GAVI Alliance to supply our cervical cancer vaccine, as part of a long-term programme to help protect girls and women against cervical cancer in the world's poorest countries.
- **More support is needed to expand access to vaccines and vaccination for children and mothers everywhere.** Every year, vaccines prevent some three million deaths and save some 750,000 children from disability. Childhood vaccinations benefit mothers too; many vaccines protect pregnant women through herd immunity, and reduce the burden of care on women. Having healthy children allows mothers more time for productive activity and reduces the costs of hospitalisation and other medical expenses that often cripple women and families financially.
- **Key stakeholders need to work together to ensure that vulnerable people have access to affordable quality healthcare.** Governments, multilateral agencies and the private sector need to collaborate to generate and sustain funding and provision for healthcare interventions. They need to work together to remove barriers to access and to support universal health coverage.
- **Maternal and child health must remain a policy priority.** Through building multi-stakeholder partnerships, all involved must create the political will to keep a spotlight on the need for continued focus on maternal and child health.
- **New sources of expertise and support need to be identified and cultivated.** Governments, multilateral agencies and the private sector should seek opportunities where they can contribute personal or professional capacity and expertise to improve maternal and child health outcomes.

## Background

### The Millennium Development Goals

The deep-rooted causes of child and maternal mortality and the need for a multifaceted approach to solving this problem and ultimately lifting populations out of poverty led to the creation of the UN Millennium Development Goals (MDGs) 4 and 5. MDG 4 commits to reduce the under 5 mortality rate by two thirds between 1990 and 2015. MDG 5 aims to reduce the rate of maternal mortality by three quarters in the same time period and to achieve universal access to reproductive health by 2015. In practical terms, the achievement of these MDGs, along with additional funds mobilised by the WHO Partnership for Maternal, Neonatal and Child Health (PMNCH)<sup>2</sup>, would translate into saving the lives of three million women and seven million children by 2015.

### Paediatric Medicines

The challenges of paediatric research, including the many scientific, ethical and logistical complexities involved, have traditionally made paediatric studies more costly than those conducted in adults. The market for paediatric medicines is inevitably also more limited than the adult market. As a result, there are far fewer paediatric indications than adult indications for medicines. A number of steps have been taken to address this.

<sup>2</sup> <http://www.who.int/pmnch/en/>

For example, the US and EU reward testing for certain indications in children with patent terms extensions and extended marketing exclusivity.

Other important initiatives include a partnership approach such as the one led by the WHO's "make medicines child size" campaign<sup>3</sup> and the development of the Essential Medicines List for children<sup>4</sup>, which aims to establish priority areas for the development and provision of paediatric medicines. Such measures to incentivise research and ensure a coordinated and consultative approach to paediatric medicines should be promoted and replicated in more countries to mitigate some of the complexities and additional costs associated with paediatric research.

Developing paediatric formulations for as many of our products as possible is an established commitment for GSK. Clinical trials to achieve these indications are conducted according to international and national regulatory requirements and in a child-friendly fashion. Save the Children and GSK have formed a long term strategic partnership<sup>5</sup> combining expertise, resources and influence to help save one million children's lives. One of the ways this partnership will help achieve this goal is by accelerating access to child-friendly medicines, which can tackle common causes of child deaths – a new formulation of chlorhexidine for example, could be used to prevent infection of the umbilical stump in newborns – a common cause of neonatal death. The partnership will also harness R&D to find new solutions to tackle major causes of child mortality, such as new affordable products to combat under nutrition in the poorest families.

### Products for Diseases Affecting Women

There is a multiplier effect to protecting the health of women (and adolescent girls), as families as a whole benefit from mothers not being taken away by illness from their duties of care during their child-rearing years and beyond.

GSK has pledged to address diseases affecting women. Post-partum haemorrhage (PPH) is the biggest cause of global maternal mortality, with the majority of deaths occurring in low income countries. Oxytocin is recommended by the WHO as first-line therapy for prevention and treatment of PPH. However, the cold-chain supply and storage required for the injectable formulation significantly limits its use outside larger facilities. Pre-term birth is a significant cause of neonatal death and complications that have far-reaching consequences for the child in later life. GSK is developing a novel treatment (*Retosiban*) to halt pre-term labour and delay delivery in women with uncomplicated pre-term labour. The clinical trials aim to demonstrate improved neonatal outcome in babies born to women treated with *Retosiban*.

In 2013 we announced a new commitment to the GAVI Alliance to supply our cervical cancer vaccine, as part of a long-term programme to help protect girls and women against cervical cancer in the world's poorest countries. Cervical cancer is a disease affecting mothers during their child-caring years and 80% of deaths occur in developing countries. Initially, the vaccine will be supplied to GAVI demonstration projects, allowing governments to gain practical knowledge, before scaling-up immunisation programmes nationally.

### The Value of Vaccinations

Only clean drinking water rivals vaccination in its ability to save lives. However, too many children and mothers are still not getting the vaccines they need. Despite the achievements of the last 50 years, around 22 million children in developing countries still do not have access to life-saving vaccines. As a result, some 19,000 children under five die every day from largely preventable causes, two thirds from infectious diseases such as pneumonia, diarrhoea and malaria. Many of these children might still be alive today if they had been vaccinated.

<sup>3</sup> <http://www.who.int/childmedicines/en/>

<sup>4</sup> [http://www.who.int/medicines/publications/essentialmedicines/4th\\_EMLc\\_FINAL\\_web\\_8Jul13.pdf](http://www.who.int/medicines/publications/essentialmedicines/4th_EMLc_FINAL_web_8Jul13.pdf)

<sup>5</sup> <http://www.gsk.com/about-us/corporate-partnerships/save-the-children-partnership.html>



Childhood vaccinations benefit mothers too; many vaccines protect pregnant women through herd immunity, and reduce the burden of care on women. Having healthy children allows mothers more time for productive activity and reduces the costs of hospitalisation and other medical expenses that often cripple women and families financially.

GSK is a world leading vaccines company involved in vaccine research, development and production and we are committed to playing our part in moving towards a world where everyone is protected against disease by having access to life-saving vaccines – no matter who they are, where they live, or how much they can afford. This means investing our resources and working with others to help tackle some of the significant access challenges.

GSK currently markets over 30 vaccines, the majority of which help protect infants and children against illnesses such as chicken pox, diphtheria, tetanus, whooping cough, measles, meningitis, mumps, polio, hepatitis, rotavirus, pneumococcal disease, gastroenteritis and rubella.

For over 20 years, we have adopted a tiered pricing system for our vaccines to ensure greater access – and have evolved that approach to recognise changes in global development and encourage pro-vaccination policies. Our approach is designed to support countries that commit to vaccination for the long term and implement programmes aimed at reaching large proportions of the target population. For the least developed countries, we work closely with GAVI and UNICEF to improve access to vaccines and vaccination. These organisations are able to purchase large volumes of vaccines for the world's poorest children at our lowest prices.

GSK is evolving its business model to deliver sustainable and affordable treatments for all people, including mothers and children, and this involves broad collaboration. Existing partnerships include:

- A partnership with Vodafone aimed at harnessing innovative mobile technology to help vaccinate more children in Africa. This initiative is designed to encourage mothers to take up vaccination services, to support health workers, to improve record keeping and to enable better management of vaccine stocks.
- Our partnership with Save the Children aimed at improving vaccination access in the developing world, in particular to the poorest or most remote or marginalised children. For example, the Partnership programme in the Democratic Republic of Congo effected the vaccination of over 2,000 children in remote and difficult to reach communities, demonstrating that even in such geo-politically challenging circumstances, national vaccination policies can be effectively implemented.
- In 2012, around 627,000 people died from malaria, most of these were African children under the age of 5. GSK's vaccine candidate - RTS,S, is being developed in partnership with PATH Malaria Vaccine Initiative (MVI), with grant monies from the Bill & Melinda Gates Foundation to MVI. If approved, RTS,S will be the world's first ever licensed vaccine against malaria.
- GSK is also working with Biological E, a leading Indian vaccines company, on a lower cost combination paediatric vaccine to protect children from polio and other infectious diseases. Through the Bio E Joint Venture, GSK will continue to make polio vaccination accessible and affordable to as many children as possible, given the switch to an Inactivated polio vaccine (IPV) requirement. GSK is a foundation supplier of the oral polio vaccine to the Global Polio Eradication Initiative and has supplied some 15 billion doses of vaccine to the programme.
- In 2013, we committed to provide an additional 240 million doses of our pneumococcal vaccine to the GAVI Alliance for use in developing countries over the next ten years. This will help to protect up to 80 million more children from pneumococcal diseases, such as meningitis and pneumonia – the leading cause of death in children under five in developing countries.
- This is in addition to the 480 million doses of the vaccine that we have already committed to GAVI through the Advance Market Commitment framework that offers heavily discounted vaccines for children living in the world's poorest countries.
- We have also committed 132 million doses of our rotavirus vaccine to GAVI over the next five years, which will help protect 60 million children against rotavirus gastroenteritis – which kills half a million children a year worldwide.

Today, around 40% of the world's children are immunised against at least one serious disease with a GSK vaccine and 80% of the vaccine doses we manufactured in 2013 went to developing countries<sup>6</sup>. However, many challenges remain and we will continue to be the trusted partner of governments, healthcare providers and other stakeholders in delivering and supporting strategies that tackle the toughest challenges to immunisation.

### Access to Affordable Quality Healthcare

The development and maintenance of adequate infrastructure is essential for healthcare interventions to be delivered to mothers and children, including capacity building for healthcare workers, especially birth attendants and trained healthcare workers. Healthcare interventions need to be adapted to mothers and children and delivered in ways suited to their needs. This involves, for example, using participatory methodologies that are owned and managed by communities, thus ensuring their healthcare preferences are taken into account and are sustainable over the long term. Where appropriate, the involvement of the private sector needs to be encouraged to form part of adapted solutions for healthcare delivery, such as the provision of quality healthcare services.

GSK is contributing to strengthening healthcare infrastructures, a key component of ensuring better access to treatments. Since 2009, GSK has reinvested 20% of profits generated in the world's least developed countries back into those countries to develop health infrastructure through training frontline health workers. Frontline health workers focus on maternal and child health and act as a link between communities and the public health system. These programmes are delivered through NGO partners (Save the Children in west and central Africa, AMREF Health Africa in east and southern Africa and CARE International in Asia) in agreement with in-country ministries of health. Thus far, we have invested a total of £15m across 34 countries. By the end of 2014, this will have resulted in the training of 15,000 frontline health workers, reaching over 5 million people. GSK has also invested £500,000 in the 1 million Community Health Workers Campaign<sup>7</sup>, a UN-led initiative to advocate for and support up-scaling of an additional 1 million Community Health Workers in sub-Saharan Africa by 2020.

### Maternal and Child Health as Policy Priorities

GSK supports the UN Secretary-General's Joint Action Plan for Women's and Children's Health<sup>8</sup>; through involvement with the Joint Action Plan, the private sector can increase its support and contribution to saving the lives of millions of women and children. All stakeholders involved in initiatives addressing mother and child health should also commit to being accountable for reporting the progress and ultimately results of their work on a regular basis with agreed measures and to share lessons learned. GSK continues to engage with governments, multilateral organisations, NGOs and local organisations to address infrastructure problems on the ground and ensure better healthcare reaches mothers and children.

We have recently developed a policy position on universal health coverage (UHC) which sets out what we see as the 8 core principles that governments may consider when determining their own approaches to UHC, including equitable access for mothers and children. We understand that countries are at very different stages of health system development, and they will need to set their own priorities and timelines towards UHC. The policies that governments implement in pursuit of UHC will impact on all stakeholders involved in improving health, including the private sector. To this end, we stand ready to work with all stakeholders to ensure a sustainable and equitable approach to UHC that also addresses the needs of mothers and children,

<sup>6</sup> GSK 2013 Corporate Responsibility Report, P20, published March 2014.

<sup>7</sup> <http://1millionhealthworkers.org/>

<sup>8</sup> [http://www.who.int/pmnch/topics/maternal/201006\\_jap\\_pamphlet/en/](http://www.who.int/pmnch/topics/maternal/201006_jap_pamphlet/en/)

**New Sources of Expertise**

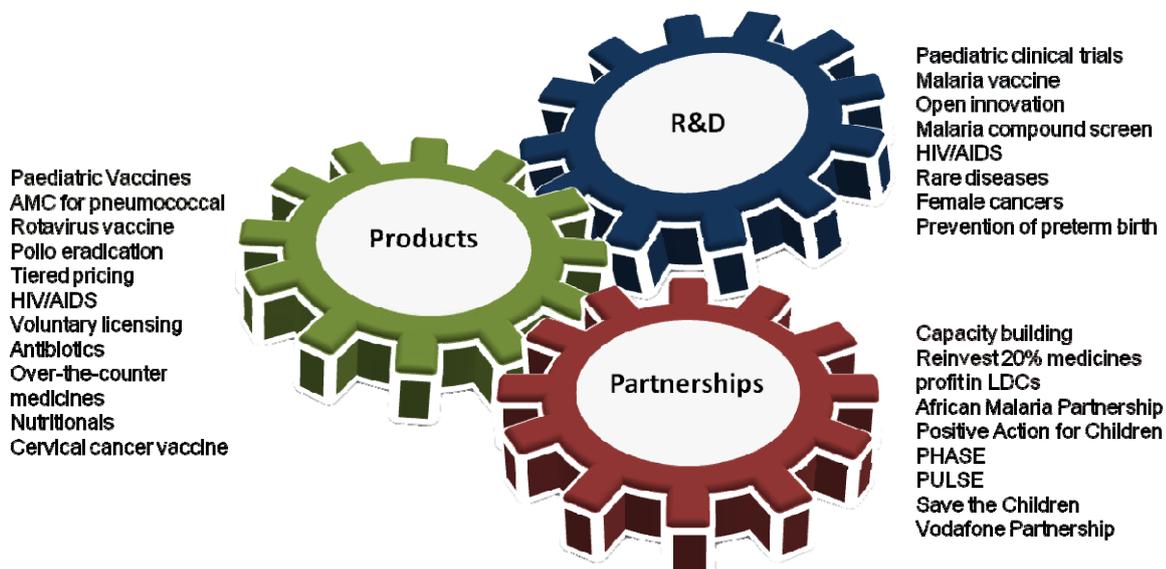
Each year, as part of the PULSE Volunteer Partnership Programme, up to 100 GSK employees work full-time for a period of three or six months with partner NGOs, many of which focus on maternal and child health such as Save the Children, AMREF and Jhpiego. GSK employees use their professional expertise in areas such as logistics, IT, finance, project management and communications to build positive, sustainable change in impoverished communities around the world. Since its launch in 2009, PULSE has empowered nearly 400 employees from across 45 different countries to work with 85 NGOs in 57 countries. In 2013 alone, nearly 100 employees from 28 countries worked with 48 partners in 36 countries.

By all stakeholders – governments, multilateral agencies, civil society and the private sector – working together, we can build on existing efforts and find new ways of researching and delivering healthcare in order to provide sustainable solutions that reduce mortality in mothers and children and break the cycle of decline from illness. Better health leads to better economic development. If we keep mothers and their families well now, we can improve the health and economy of future generations. The global community must maintain and increase momentum to improve the health of mothers and children, and GSK remains committed to playing its part in the global effort to reach the MDGs 4 and 5 through our R&D, our products and our partnerships.

**GSK's Contribution**

GSK's contribution towards child and maternal health is wide-ranging and sustainable. It spans our whole portfolio, as well as the entire supply chain from R&D to products to partnerships for delivery:

- **In R&D**, we are committed to researching medicines and vaccines addressing the specific needs of children and women and ensuring paediatric trials are conducted to a high and child-friendly standard. We are actively researching preventive and curative measures against malaria, HIV/AIDS and cancer. A new R&D Unit has been established to focus on innovative approaches to address unmet medical needs in maternal and neonatal health.
- **In our product portfolio**, we have a strong track record in disease prevention for children as well as ensuring our treatments are safe and effective for them. We are working to make our medicines and vaccines relevant and more widely available to the developing world's mothers and children. Our consumer healthcare division also makes a contribution to the daily lives of children through Over-The-Counter medicines and nutritional products.
- **In our partnerships**, we strive to engage with multilateral organisations, NGOs and civil society to address financing, delivery and infrastructure problems. We deploy our skills and capabilities to create maximum impact through partnerships. With our partners, we focus on capacity-building with healthcare workers and education of mothers and children to achieve lasting reach to communities.





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### The Post-2015 Agenda

In terms of the post-2015 agenda, one of the 12 Universal Goals in *The Report of the High-Level Panel of Eminent Persons on the Post-2015 Development Agenda*<sup>9</sup>, aims to 'Ensure Healthy Lives'; this focuses on ensuring universal access to basic healthcare in order to achieve the outcomes; these include addressing infant and maternal mortality rates. In the Secretary General's UNSG Report – *A Life of Dignity for All*<sup>10</sup>, to 'Improve Health' is listed as a key transformative action; this also aims to end preventable maternal and child deaths.

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<sup>9</sup> <http://www.post2015hlp.org/the-report/>

<sup>10</sup> <http://www.un.org/millenniumgoals/pdf/A%20Life%20of%20Dignity%20for%20All.pdf>