Merck’s Position Statement – Fertility

Why it matters

The World Health Organization (WHO) defines infertility as the inability to carry a pregnancy to term or to conceive after 12 months or more of regular unprotected sexual intercourse.\(^1\) According to the American Society for Reproductive Medicine (ASRM) and the Centers for Disease Control and Prevention (CDC), this time is reduced to six months if the woman is over the age of 35.\(^2,3\) More than 72.4 million women are infertile.\(^4\) According to WHO, 15 percent of reproductive-aged couples are affected by infertility.\(^5\) Infertility is not only a developed world condition—one in every four couples in developing countries has been found to be affected by infertility.\(^6\)

While infertility can be a long and uncertain journey, many patients who complete an infertility treatment ultimately succeed in having a child. There are many fertility treatments available to women who would like to conceive:

- Medications to stimulate ovulation,
- Surgery, such as procedures to repair fallopian tubes or remove blockages in the tubes, and
- Assisted Reproductive Technology (ART), such as in vitro fertilization and intrauterine insemination (IUI).\(^7\)

Eight out of ten women under the age of 38 who receive ART treatments are able to give birth.\(^8\) Yet, only a small fraction of families—approximately 15 percent of self-diagnosed women with fertility problems—receive ART.\(^9\)

Increasingly, countries are developing policies and programs to support families in their efforts to have a child. In several countries, public health institutions are involved in addressing infertility. Despite this, additional epidemiologic and prevention research, program development and evaluations, and public education are required to address challenges stemming from infertility.\(^10\)

There exists a large unmet need for infertility treatments due to a lack of awareness as well as stigma and discrimination issues related to a couple’s inability to conceive. Especially in developing countries, there is a lack of capability and capacity (e.g., fertility clinics) to access high quality fertility medicines and therapies.

With many countries experiencing rapidly aging populations, there is mounting pressure to address demographic challenges. Additionally, in many regions, fertility rates are declining, partly because

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9 Merck Serono; Psyma research; ISS; HFEA; Team
couples are choosing to have children at a later age when it is harder to conceive. In 2012, fertility rates globally were below the replacement rate of 2.1 births per woman, most notably:

- EU28: 1.58,
- China: 1.66,
- Japan: 1.41, and
- Russia: 1.69.\(^{11}\)

In fact, amongst the OECD countries, only Mexico and Israel have fertility rates sufficient to maintain a steady population.

Recently, an objective study in Spain on the fiscal implications of public funding of ART found that each euro invested in subsidizing ART reverts into fiscal benefits of €5.\(^{12}\) The compelling economic arguments are good reasons for increasing access to infertility treatments, notwithstanding its psychological benefit for infertile couples.

**Merck Position**

- Merck partners with governments, professional organizations, and advocacy groups in the development of comprehensive national plans for infertility prevention, detection, and management. Merck believes that national infertility plans should include a strong evidence-based communication and public education component.

- Merck is working towards ensuring equal access to fertility treatments. We partner with governments to reduce barriers to access. For example, we are strengthening national data collection systems to ensure proper recording of national infertility burden data.

- Merck believes that Ministries of Health play a key role in educating couples about infertility and the availability of treatment options.

- Merck advocates in favour of strategies that integrate infertility diagnosis and treatments in reproductive health services.

- Merck realizes that affordability is a challenge for many consumers in the fertility marketplace. We encourage public and private funding given both the compelling social and economic arguments.\(^{12}\)

- Merck advocates for increased insurance coverage for infertility treatments. Greater coverage improves patient choice and access, which increases the likelihood of healthier pregnancies and healthier babies. This, in turn, affords cost savings for the entire health care system.

- Merck strongly discourages the inappropriate use of fertility therapies, as they can have a negative impact on a woman’s health. We also monitor and respect ethical codes of conduct and legal frameworks for fertility care where we operate.

- Merck supports initiatives that improve quality of treatment, including those that establish quality standards and offer medical education and training to health care providers and their staff.

- Merck has more than 60 years of expertise in the fertility-space, pioneering innovative science and technologies, and deep consumer and professional understanding of infertility.

- Merck is the world leader in fertility treatments. We develop and provide innovative products and devices, as well as patient care support services that help infertile couples at every stage of the fertility treatment cycle.

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Since 2010, Merck has awarded grants in fertility innovation totalling up to €8 million. The Grant for Fertility Innovation (GFI) funds translational and innovative research projects that could potentially improve fertility treatment outcomes.

As a leader and innovator, Merck supports ongoing advancement in ART by going beyond drugs with innovative technologies to for example, define gametes viability, embryo implantation potential, and uterine receptivity. Merck took action by opening a Fertility Technologies group to bring key technologies to reality.

About Merck
Merck is a leading science and technology company in healthcare, life science and performance materials. Around 40,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2014, Merck generated sales of €11.3 billion in 66 countries. Founded in 1668, Merck is the world’s oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck, Darmstadt, Germany holds the global rights to the Merck name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, EMD Millipore and EMD Performance Materials.

Merck’s biopharma business
With headquarters in Darmstadt, Germany, Merck’s biopharma business offers leading brands in 150 countries to help patients with cancer, multiple sclerosis, infertility, endocrine and metabolic disorders as well as cardiovascular diseases. Merck discovers, develops, manufactures and markets prescription medicines of both chemical and biological origin in specialist indications. We have an enduring commitment to deliver novel therapies in our core focus areas of neurology, oncology, immuno-oncology and immunology. For more information, please visit http://biopharma.merckgroup.com/en/index.html