

Fertility

- Principle -

Rationale

International ethical views, laws as well as medical practice for the treatment of infertility differ and are furthermore subject to changes in society and science as well as between countries. Merck KGaA, Darmstadt, Germany as a global company that operates in different countries around the world needs a clear framework addressing ethical and legal concerns in this heterogeneous environment. To provide clarity, Merck KGaA, Darmstadt, Germany has developed the following company Principle.

Objective

This company Principle provides background information on Fertility treatments and the current position of the company on the research and application of drugs and technologies in the treatment of infertility.

New Merck KGaA, Darmstadt, Germany technologies, services and therapies to improve fertility treatment outcomes as well as collaborations in this area undergo internal review, in close relationship with, seeking and taking advice, from the Merck KGaA, Darmstadt, Germany Bioethics Advisory Panel (MBAP).

This Principle undergoes regular review including the Merck KGaA, Darmstadt, Germany Bioethics Advisory Panel (MBAP).



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1. Background

Merck KGaA, Darmstadt, Germany is a global provider of drugs and technologies used in fertility treatments.

There is a significant need for improved technologies and services in fertility treatment, which is clearly articulated by healthcare professionals. Merck KGaA, Darmstadt, Germany is dedicated to addressing the need for high consistency and quality standards in fertility treatment.

As a corporation domiciled in Germany, Merck KGaA, Darmstadt, Germany is subject to the application of the German Embryo Protection Act (GEPA).

At the same time, international ethical views, laws as well as medical practice for the treatment of infertility differ and are furthermore subject to changes in society and science.

Merck KGaA, Darmstadt, Germany as a global company also respects laws and standards in other countries as Merck KGaA, Darmstadt, Germany respects laws and standards in Germany and takes both into consideration for decision making.

2. Merck KGaA, Darmstadt, Germany Position

As a company with a long standing heritage ethical standards are very important for us. Patients are in the focus of all that we do. In Merck KGaA, Darmstadt, Germany we want to improve patients' lives with innovative specialty medicines, leading brands and high-value solutions.

With regard to fertility treatments we want to support patients with high quality diagnostic and treatment options, including drugs, technologies and services, aimed at improving patients' treatment experiences and live-birth-rates. In an environment of conflicting interests and diverse views we strive for patient-centered solutions.

In doing this, we follow the following guiding principles:

- We recognize the desire of a person / couple to have a child.
- We are committed to providing high-quality, innovative products, services and solutions for patient care. Where appropriate, we are committed to generate additional data on the benefits for clinics, patients and outcomes.



- We promote the responsible application of our products and good medical practice to prevent misuse.
- We respect and do not interfere with the relationship between doctors and patients, based on patients' autonomy and physicians' medical expertise. As a consequence we will not control/track or get otherwise involved in the particular medical uses of our products in the context of the doctor patient relationship.
- We seek to broaden equitable access to high-quality treatments.
- We acknowledge the international environment with diverse ethical views, policies and medical standards. We respect local laws and jurisdiction. Given the changing scientific and social understanding of reproductive technologies, as an ethically responsible global company, we continually revisit the activities that we will pursue.

Merck KGaA, Darmstadt, Germany will evaluate these guiding principles regularly and reconsider the position based on latest scientific results.

3. Current Engagement

Merck KGaA, Darmstadt, Germany is a leading fertility company and offers recombinant versions of the three natural hormones needed to treat infertility as well as a broad and clinically proven portfolio of fertility drugs covering all key steps of the reproductive cycle.

With our Fertility Technologies we have set out to overcome current challenges caused by variation in clinical and laboratory practices and techniques, ultimately aiming at improving treatment outcomes in the best interest of patients.

We are continuously investing in external research and product development through collaborations, alliances, in-licensing opportunities and potential acquisitions in line with our strategy.

At the same time and in light of the ethical principles outlined above, Merck KGaA, Darmstadt, Germany will not actively pursue the following practices or procedures:

- Reproductive cloning of human beings
- Production of human embryos solely for research purposes



- Intervention for non-medical reasons e.g. genetic diagnoses for socially desirable features like eye/hair color, gender selection for non-medical reasons
- Use of genome editing in human embryos
- Creation and use of human artificial gametes for reproductive purposes

As a consequence, we will also not hold shares or have board seats in companies who engage in such activities. We will not support or finance such activities of third parties and will not enter into collaborations with third parties to pursue such activities.

4. Outlook

Merck KGaA, Darmstadt, Germany recognizes the sensitive nature of certain Fertility treatment practices and related research.

In order to challenge the internal assessment of the Fertility principles for Merck KGaA, Darmstadt, Germany and to constantly review this position according to latest scientific, legal and ethical insights, Merck KGaA, Darmstadt, Germany has installed a Merck KGaA, Darmstadt, Germany Bioethics Advisory Panel (MBAP) in 2011.

The MBAP consists of a group of external renowned experts from the fields of sciences, bioethics and law. This board advises Merck KGaA, Darmstadt, Germany on a regular basis on important topics with ethical and legal impact, including embryo technology, stem cell research, and genome editing.



5. Glossary and Definitions

Abbreviation	Definition
ART	Artificial Reproductive Technologies
GEPA	German Embryo Protection Act
MBAP	Merck KGaA, Darmstadt, Germany Bioethics Advisory Panel

- **“Principle”: Corporate definition**

A Principle specifies the basic rules for Corporate Governance which needs to be complied with by all subsidiaries of Merck KGaA, Darmstadt, Germany (“Subsidiaries”). Its purpose is to ensure a consistent corporate governance framework for all Subsidiaries worldwide. A Principle defines corporate governance structures and corporate governance responsibilities. It does not address organizational responsibilities.

