

<i>Charter</i>	Merck KGaA, Darmstadt, Germany
Fertility Principles	
Document Unit (Owner) : (CA) Corporate Affairs Applicability : Merck KGaA, Darmstadt, Germany, Group Approved by : Executive Board, GL	

Fertility principles

our position

Merck KGaA, Darmstadt, Germany, aims 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, devices 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.



Fertility principles

guiding principles

 Merck KGaA, Darmstadt, Germany, recognizes the desire of a person or couple to have a child.

 We seek to broaden equitable access to high-quality treatments.

 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 its products and good medical practice to prevent misuse.

 We acknowledge the international environment with diverse moral 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 it pursues.

 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 its products in the context of the doctor patient relationship.



Fertility principles our safeguards for research and applications



Merck KGaA, Darmstadt, Germany, will not pursue the reproductive cloning of human beings.



In accordance with the German Embryo Protection Act and consistent with current guidelines, we will not engage in the use of genome editing in human embryos and clinical applications of germline interventions in humans. For fertility research involving genome editing, careful ethical and legal assessments are also made in accordance with our Genome Editing Principles.



In accordance with the German Embryo Protection Act we will currently not engage in the production of human embryos for research purposes or in deriving hESCs.



We will not engage in interventions for non-medical reasons (e.g., genetic diagnoses for socially desirable features like eye or hair color, or gender selection).



For fertility research involving stem cells, careful ethical and legal assessments are also made in accordance with our Stem Cell Principles.



Consistent with current guidelines, we will not engage in the creation and use of human artificial gametes for reproductive purposes.



For fertility research with animals, careful ethical and legal assessments are also made in accordance with our Policy on Animal Welfare.



Fertility principles our safeguards as a partner and supplier



Prior to finalizing any agreement with a partner, Merck KGaA, Darmstadt, Germany, will review and comply with ethical, regulatory, and legal requirements related to and contained within these Principles. We will make these Fertility Principles public and expect its customers and partners to comply with the provisions of this section.



We will not deliver any of its fertility products and services, if we become aware of any projects by customers, partners or institutes directed at the creation of human embryos for research purposes or the cloning of human beings.



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



1. Objective

The public perception, laws and medical practice for the treatment of infertility differ between geographies and are furthermore subject to changes driven by societal and scientific developments. Research, clinical and commercial activities in this field need careful evaluation of ethical and legal concerns and require a clear framework within the Merck KGaA, Darmstadt, Germany, Group, a global company that operates in different countries around the world. Therefore, Merck KGaA, Darmstadt, Germany, has developed the following company Principles.

2. Scope

These company Principles provide 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.

All Merck KGaA, Darmstadt, Germany, employees working within the area of fertility treatments are responsible for understanding and abiding by these Fertility Principles. In addition, Merck KGaA, Darmstadt, Germany, expects that third parties are up to date with respect to the on-going deliberations regarding the ethical aspects of fertility treatments.

New Merck KGaA, Darmstadt, Germany, technologies, services and therapies as well as collaborations in this area undergo regular internal review, in close relationship with, seeking and taking advice, from the Merck KGaA, Darmstadt, Germany, Ethics Advisory Panel for Science and Technology (MEAP), formerly Merck KGaA, Darmstadt, Germany, Bioethics Advisory Panel (MBAP).

3. Executive Summary

Merck KGaA, Darmstadt, Germany, acknowledges the ethical controversies surrounding fertility treatments and has instituted safeguards for research and development as well as commercialization of drugs, technologies, devices and services for fertility treatments. These safeguards stipulate that Merck KGaA, Darmstadt, Germany, does not pursue the reproductive cloning of human beings, the production of human embryos for research purposes, in interventions for non-medical reasons, the use of genome editing in human embryos, and in the creation and use of human artificial gametes for reproductive purposes. This includes collaborations or grants involving such activities. Prior to finalizing any agreement with a partner, Merck KGaA, Darmstadt, Germany, will review and comply with ethical, regulatory, and legal requirements related to and contained within these Principles. Merck KGaA, Darmstadt, Germany, will not deliver any of its fertility products and related services, if Merck KGaA, Darmstadt, Germany, becomes aware of any projects by customers, partners or institutes directed at research, clinical and commercial activities that are prohibited by Merck KGaA, Darmstadt, Germany, as specified here (see. 5.2 below).

4. Background

Merck KGaA, Darmstadt, Germany, is a global provider of drugs, and technologies, devices and services used in fertility treatments. There is a significant need for improved drugs, technologies, devices 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, KGaA is subject to the application of the German Embryo Protection Act (GEPA). At the same time, international moral 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.

5. Merck KGaA, Darmstadt, Germany, Position

Merck KGaA, Darmstadt, Germany, aims to improve patients' lives with innovative specialty medicines, leading brands and high-value solutions. With regard to fertility treatments Merck KGaA, Darmstadt, Germany, wants to support patients with high quality diagnostic and treatment options, including drugs, technologies, devices and services, aimed at improving patients' treatment experiences and live-birth-rates. In an environment of conflicting interests and diverse views Merck KGaA, Darmstadt, Germany, strives for patient-centered solutions.

In doing this, Merck KGaA, Darmstadt, Germany, adheres to the following guiding principles:

- Merck KGaA, Darmstadt, Germany, recognizes the desire of a person or couple to have a child.
- Merck KGaA, Darmstadt, Germany, is committed to providing high-quality, innovative products, services and solutions for patient care. Where appropriate, Merck KGaA, Darmstadt, Germany, is committed to generate additional data on the benefits for clinics, patients and outcomes. Merck KGaA, Darmstadt, Germany, promotes the responsible application of its products and good medical practice to prevent misuse.
- Merck KGaA, Darmstadt, Germany, respects and does not interfere with the relationship between doctors and patients, based on patients' autonomy and physicians' medical expertise. As a consequence, Merck KGaA, Darmstadt, Germany, will not control, track or get otherwise involved in the particular medical uses of its products in the context of the doctor patient relationship.
- Merck KGaA, Darmstadt, Germany, seeks to broaden equitable access to high-quality treatments.
- Merck KGaA, Darmstadt, Germany, acknowledges the international environment with diverse moral views, policies and medical standards. Merck KGaA, Darmstadt, Germany, respects local laws and jurisdiction. Given the changing scientific and social understanding of reproductive technologies, as an ethically responsible global company, Merck KGaA, Darmstadt, Germany, continually revisits the activities it pursues.

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

5.1. 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. Merck KGaA, Darmstadt, Germany, is continuously investing in external research and product development through collaborations, alliances, in-licensing opportunities and potential acquisitions in line with our strategy.

5.2. Safeguards for fertility research and applications

Merck KGaA, Darmstadt, Germany, acknowledges the ethical controversies surrounding fertility treatments. In doing so, Merck KGaA, Darmstadt, Germany, complies with the following:

- Merck KGaA, Darmstadt, Germany, will not pursue the reproductive cloning of human beings.



- In accordance with the German Embryo Protection Act Merck KGaA, Darmstadt, Germany, will currently not engage in the production of human embryos for research purposes or in deriving hESCs.
- Merck KGaA, Darmstadt, Germany, will not engage in interventions for non-medical reasons (e.g., genetic diagnoses for socially desirable features like eye or hair color, or gender selection).
- In accordance with the German Embryo Protection Act and consistent with current guidelines, Merck KGaA, Darmstadt, Germany, will not engage in the use of genome editing in human embryos and clinical applications of germline interventions in humans. For fertility research involving genome editing, careful ethical and legal assessments are also made in accordance with Merck KGaA, Darmstadt, Germany,'s Genome Editing Principles.
- Consistent with current guidelines, Merck KGaA, Darmstadt, Germany, will not engage in the creation and use of human artificial gametes for reproductive purposes.
- For fertility research involving stem cells, careful ethical and legal assessments are also made in accordance with Merck KGaA, Darmstadt, Germany,'s Stem Cell Principles.
- For fertility research with animals, careful ethical and legal assessments are also made in accordance with Merck KGaA, Darmstadt, Germany,'s Policy on Animal Welfare.
- Prior to finalizing any agreement with a partner, Merck KGaA, Darmstadt, Germany, will review and comply with ethical, regulatory, and legal requirements related to and contained within these Principles. Merck KGaA, Darmstadt, Germany, will make these Fertility Principles public and expect its customers and partners to comply with the provisions of this section.
- Merck KGaA, Darmstadt, Germany, will not deliver any of its fertility products and services, if Merck KGaA, Darmstadt, Germany, becomes aware of any projects by customers, partners or institutes directed at the creation of human embryos for research purposes or the cloning of human beings.
- Merck KGaA, Darmstadt, Germany, will not hold shares or have board seats in companies who engage in activities outlined here. Merck KGaA, Darmstadt, Germany, will also not support or finance such activities of third parties and will not enter into collaborations with third parties to pursue such activities.

6. Outlook

Merck KGaA, Darmstadt, Germany, will periodically review this position according to latest scientific, ethical, and legal insights. The MEAP regularly advises on important topics with ethical and legal impact related to fertility treatments.

7. Glossary

Abbreviations	Definition
ART	Artificial Reproductive Technologies
GEPA	German Embryo Protection Act
MBAP	Merck KGaA, Darmstadt, Germany, Bioethics Advisory Panel
MEAP	Merck KGaA, Darmstadt, Germany, Ethics Advisory Panel for Science and Technology

8. References

Group Standard "iMS-Document Management" (*ManGo Doc ID 20043334*)



9. Revision History

Version Number	Change short description	Replacement of Document
1.0	First Version	N/A
2.0	Updated according to new ISSCR guidelines; Merck KGaA, Darmstadt, Germany, position unchanged.	First Version

