FemTech Apps & AI: Regulatory Challenges

AI Tech & Policy Talks – Digital Law Center, University of Geneva

25 March 2025

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Overview

I. FemTech (Apps): Notion, Potential, and Risks

II. Legal Framework

III. AI Regulation

IV. Challenges and Perspectives

I. FemTech (Apps): Notion, Potential, and Risks

redoxengine.com

– "FemTech"

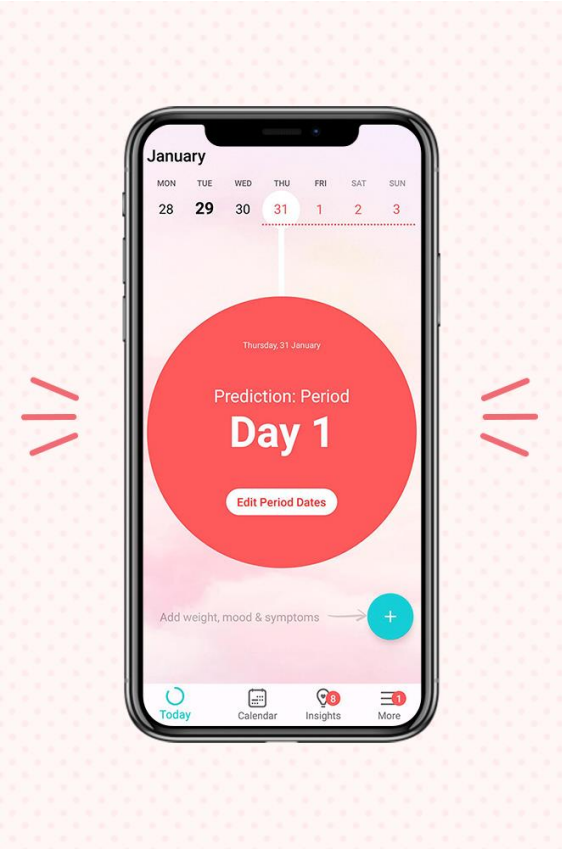
- "**Female Technology**" ➔ *technologies tailored to the health of those with female reproductive organs*
- Term coined by **Ida Tin** (2016)
- **Variety** of products and areas:

freshcodeit.com

I. FemTech (Apps): Notion, Potential, and Risks

– FemTech Apps and AI

- Health tracking technologies "specifically marketed at women"
- Rapid progress in AI and digitalization, societal shifts, other events
- **Focus ➔ Fertility tracking apps** (menstruation apps; reproductive health apps)



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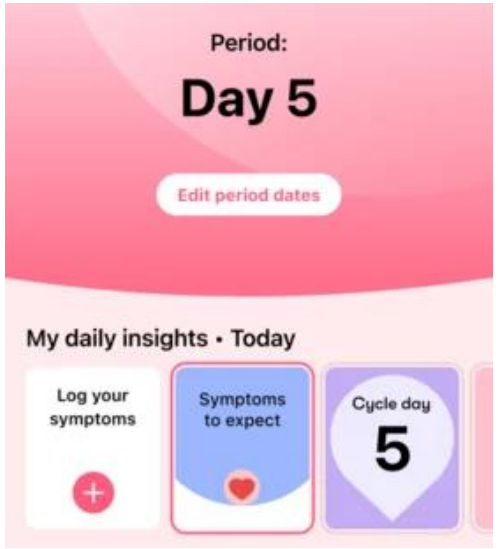
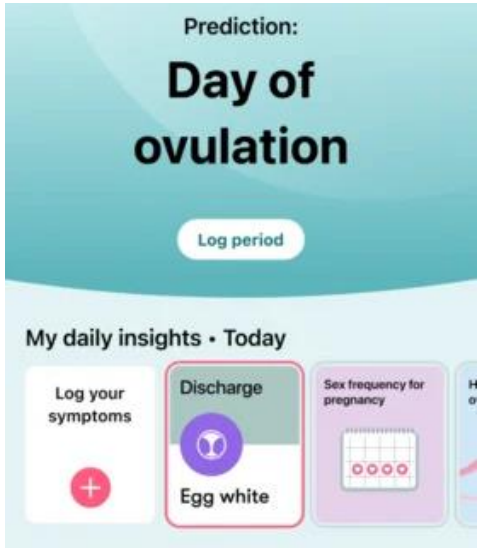




flo.health.com

I. FemTech (Apps): Notion, Potential, and Risks

– Potential and Risks of Fertility Tracking Apps

- **Potential:**
  - ➢ Individual empowerment and better control over **reproductive health**
  - ➢ **Public health potential**
- **Risks:**
  - ➢ "**Double accuracy issue**" (Mehrnezhad et al. 2024) ➔ reliability issue by app & reliance of self-reported data and statistical averages ➔ contraceptive failure
  - ➢ **Data privacy and security** ➔ e.g. commercialization of data, surveillance and control
  - ➢ **Other issues**, e.g. discrimination, tracking fatigue

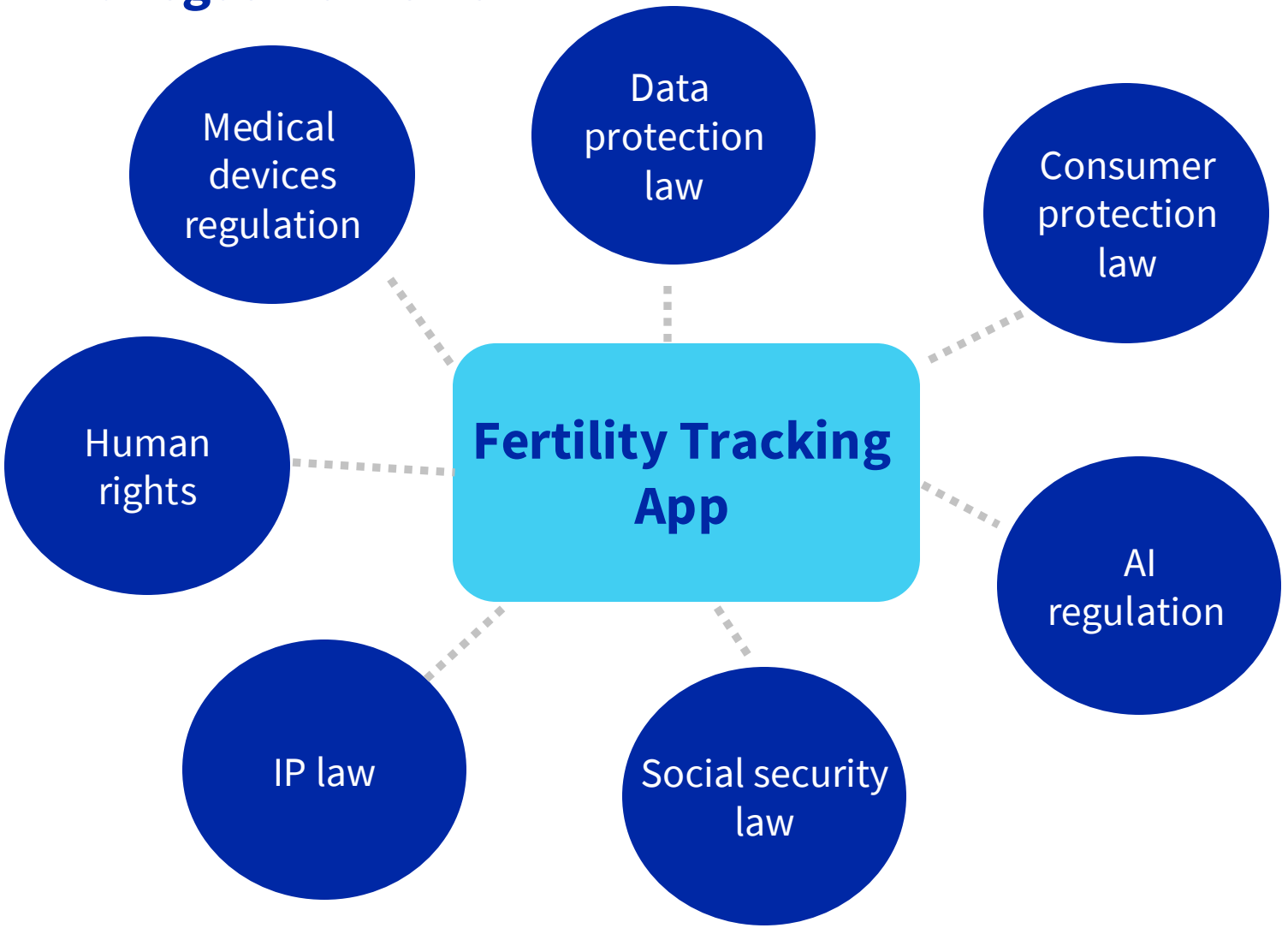
➔ ***Paradox of control***

II. Legal Framework

– Navigating a Regulatory Maze

- FemTech sector "**yet to be properly regulated**" (Scatterday 2022; Mehrnezhad et al. 2022)
- UK rules on fertility related FemTech described as "**complete regulatory failure**" (McMillan 2022)
- ***Reasons for criticism:***
  - ➢ *Existing legal frameworks **not tailored** to address challenges specific to FemTech*
  - ➢ ***Fragmented** legal frameworks*

II. Legal Framework



- *Regulatory gaps*
- *Noncompliant practices*
- *Lack of enforcement*
- *Limited research and guidelines on safe use*

*+**Added difficulty** due to different agencies with varying competencies and oversight & Swiss federalist system*

II. Legal Framework

– Medical Devices Regulation

- **Qualification of app as medical device**

  ➢ Criteria include the app serving a **medical purpose ➔ intended purpose** as specified by manufacturer (see also Art. 3, para. 2, lit. a Swiss Medical Devices Ordinance (MedDO) and Art. 2(1) EU Medical Devices Regulation 2017/745 on devices for control or support for conception)

  ➢ Consequence: **classification into categories** (I, IIa, IIb, III) with varying requirements depending on risk level, e.g. third-party conformity assessment (see Swiss Federal Therapeutic Products Act; MedDO and its Art. 15 ➔ classification in accordance with EU rules; see not. EU-MDR)

➔ ***Significant control of manufacturers***

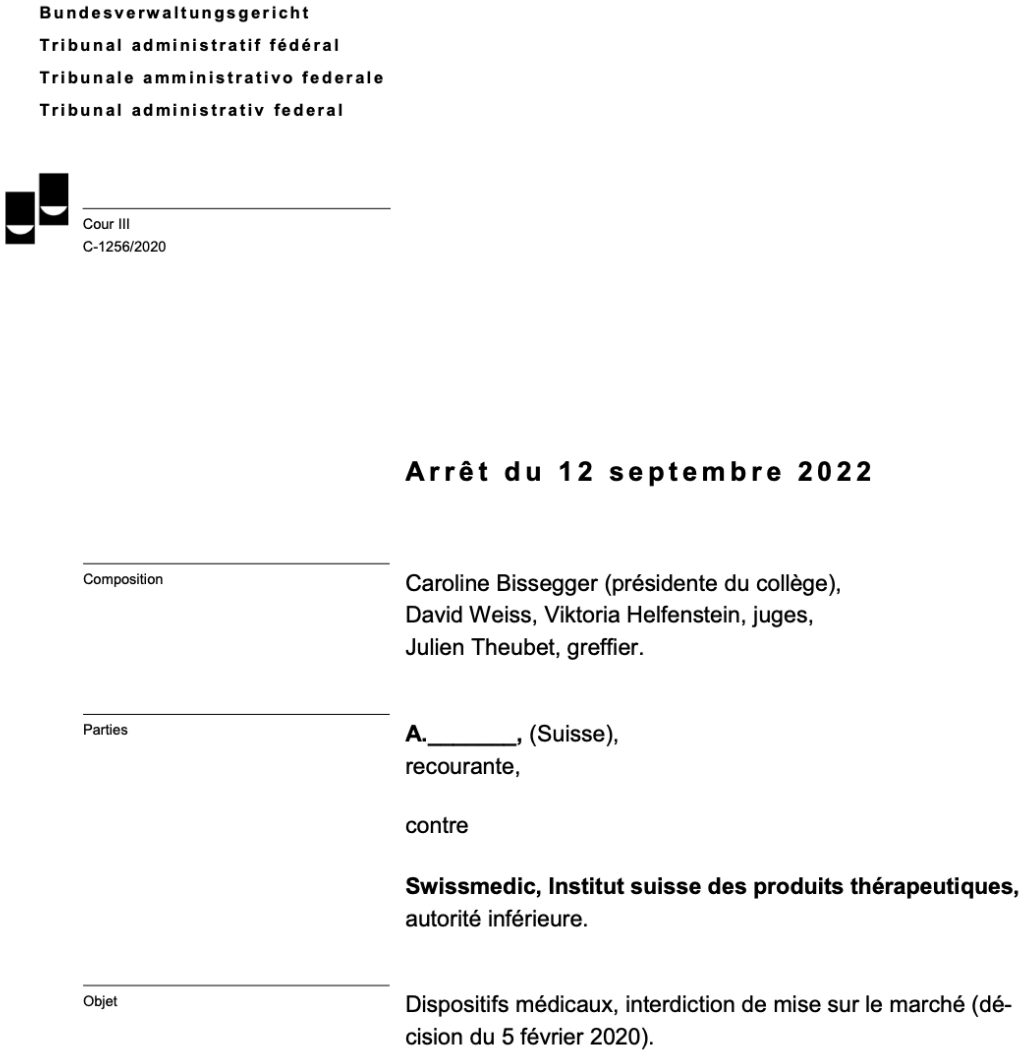
"***It's the manufacturer that decides*** *if an app qualifies as a medical device*" (free translation)

II. Legal Framework

– Medical Devices Regulation

- **Swiss case law: Broad and stringent approach** to the classification* of fertility tracking apps as medical devices (Swiss Federal Administrative Court Decision C-1256/2020 of 12 September 2022)
  - ➢ "Software applications designed to **prevent pregnancy or facilitate conception** are **class IIb medical devices**" (Op. cit., no. 5.2; free translation)
  - ➢ "It has to be said that **contraception and conception are two aims of the same kind**, namely the reproduction of the human species, and **represent two sides of the same coin**." (Swiss Federal Administrative Court Decision C-669/2016 of 17 September 2018, no. 6.3.1; free translation)

**For qualification, see Art. 3, para. 2, lit. a MedDO and Art. 2(1) EU-MDR*



Bundesverwaltungsgericht
Tribunal administratif fédéral
Tribunale amministrativo federale
Tribunal administrativ federal

Cour III
C-1256/2020

Arrêt du 12 septembre 2022

Composition
Caroline Bissegger (présidente du collège), David Weiss, Viktoria Helfenstein, juges, Julien Theubet, greffier.

Parties
A._____, (Suisse), recourante,

contre

Swissmedic, Institut suisse des produits thérapeutiques, autorité inférieure.

Objet
Dispositifs médicaux, interdiction de mise sur le marché (décision du 5 février 2020).

II. Legal Framework

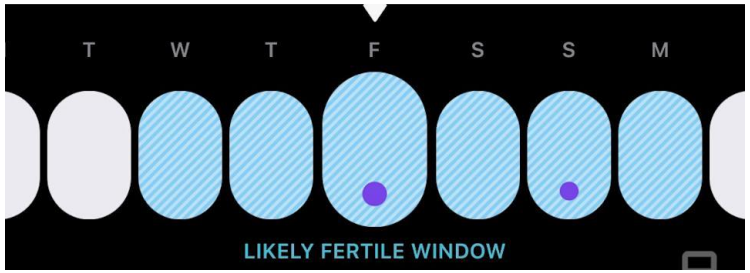
– Medical Devices Regulation

- **EU and Swiss rules and guidance**
  - ➢ **Classification** of apps aimed at contraception vs. fertility control:

    ➔ Apps for **contraception**: Class IIb medical devices (Rule 15 of Annex VIII EU-MDR and Art. 15 MedDO; MDCG 2021-24, p. 44; see also MDCG 2019-11, p. 14, no. 4.2.4)

    ➔ Apps for **fertility control/conception**: Class I medical devices ➔ lighter regulatory requirements (MDCG 2021-24, p. 48; see also MDCG 2019-11, no. 12 Annex VI, p. 28; Swissmedic, Information sheet Medical Device Software. 2024, no. 5.1, p. 7)

    ➔ ***An inconsistency?*** *Easy to use conception app for contraception!* (Pilottin 2023)



engadget.com

II. Legal Framework

Clue Period Tracker & Calendar 12+
Cycle & Pregnancy Calculator
BioWink GmbH

#47 in Health & Fitness
★★★★½ 4.7 • 24K Ratings

Free · Offers In-App Purchases

App Store for iPhone
Switzerland – 13 March 2025

"**Note: Clue should *not* be used as a contraceptive.** Clue is made to help people understand their menstrual and reproductive health by tracking their data, as well as predicting fertile days to aid conception."

II. Legal Framework

– Medical Devices Regulation

- **Market surveillance**
  - ➢ Apps landscape as an "**indescribable jungle**" (Swissmedic 2023)
  - ➢ Swissmedic primarily acts in **response to (rare!) reports** by the public
  - ➢ Many manufacturers are **unaware** that their solutions **might qualify as medical devices**

III. AI Regulation

– Swiss Legal Framework

- **No (overarching) AI-specific legislation**
- February 2025: **AI regulation strategy** announced (Swiss Federal Council Press Release on AI regulation, 12 Feb. 25; see also Swiss Federal Office of Communication OFCOM, *Overview of artificial intelligence regulation: Report to the Federal Council*, Feb. 2025)
  - ➢ Ratification of **Council of Europe Convention on AI** (Council of Europe Framework Convention on Artificial Intelligence and Human Rights, Democracy and the Rule of Law, 2024)
  - ➢ **Sectorial approach** ➔ work on regulation of specific sectors, including ***healthcare*** (no comprehensive and detailed regulation planned)
  - ➢ **Non-legally binding measures** to be developed

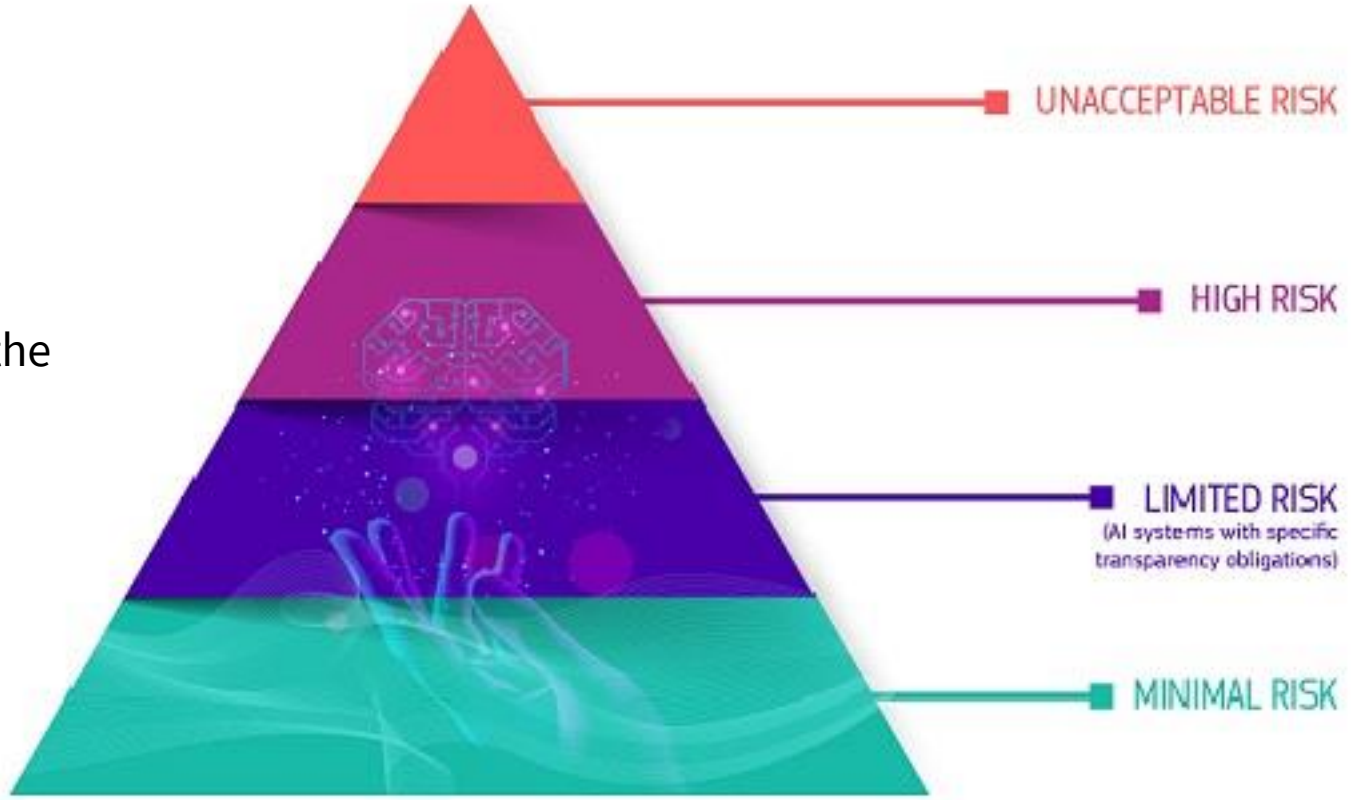
➔ ***Bill to be drafted by end of 2026***

➔ ***Safeguarding fundamental rights*** *as one of the objectives*

III. AI Regulation

– EU AI Act*

- Came into force on **1 August 2024**
- **Broad scope ➔** extraterritorial effect
- **Risk-based approach**
  - ➢ Varying requirements depending on the risk category



digital-strategy.ec.europa.eu

*Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act)

III. AI Regulation

– The Interplay Between Medical Devices Regulation and the EU AI Act

- AI medical devices that are required to undergo a third-party conformity assessment under the EU Medical Devices Regulation ➔ considered **high-risk systems** (see Art. 6, para. 1, Annex II and preamble no. 50 EU AI Act)
  - ➢ AI medical devices of **risk class IIa or higher** are considered **high-risk systems** ➔ *stringent requirements, e.g. risk management, data governance, human oversight* (see Art. 8 et seq. EU AI Act)
  - ➢ AI medical devices of **risk class I** & health-related AI systems not **considered as medical devices** ➔ *potentially only subject to certain obligations, e.g. transparency requirements or AI literacy measures* (see Art. 50 and Art. 4 EU AI Act) ➔ *no comprehensive oversight and accountability mechanisms*

III. AI Regulation

– The Interplay Between Medical Devices Regulation and the EU AI Act

- Consequence: **Oversight of AI medical devices largely depends on the manufacturer**

  ➔ ***Issue of intended purpose "renewed in importance"*** *due to the interplay between the EU AI Act and Medical Devices Regulation and the latter again* ***leaves manufacturers with "considerable discretion"*** *over the requirements to which a solution is subject*
  (Palmieri/Goffin 2023; see also Pilottin 2024)

- **Fertility tracking apps** using AI
  - ➢ Impact of app purpose for contraception vs. conception

    ➔ *Renewed question of the* ***relevance of this distinction***

IV. Challenges and Perspectives

– Selected Key Regulatory Challenges

- **Intended purpose** issue ➔ medical devices regulation & AI regulation interplay
- **Distinction** contraception vs. conception apps ➔ inconsistent?
- Possibly rapid **change of use** in case of AI evolving with time? (see Pilottin 2024; Vokinger/Hwang/Kesselheim 2022; Yu 2022)
- **Insufficient** (pre-market and) post-market **surveillance?**
- **Fundamental rights** of the special category of users

IV. Challenges and Perspectives

– Future Perspectives

- **Further guidance and information**
  - **EU AI Act** ➔ awaited guidance
  - **Swiss AI regulation** ➔ awaited draft bill (end of 2026)
- AI regulation provides for **welcome additional requirements** aiming at ensuring the **safe and ethical use** of these technologies
- How can regulatory frameworks be designed to adequately protect users while enabling fertility tracking apps to reach their full **potential**?
- Role of **awareness and education**

Thank you very much for your attention!

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